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(54) **SURGICAL ACCESS SYSTEM AND RELATED METHODS**

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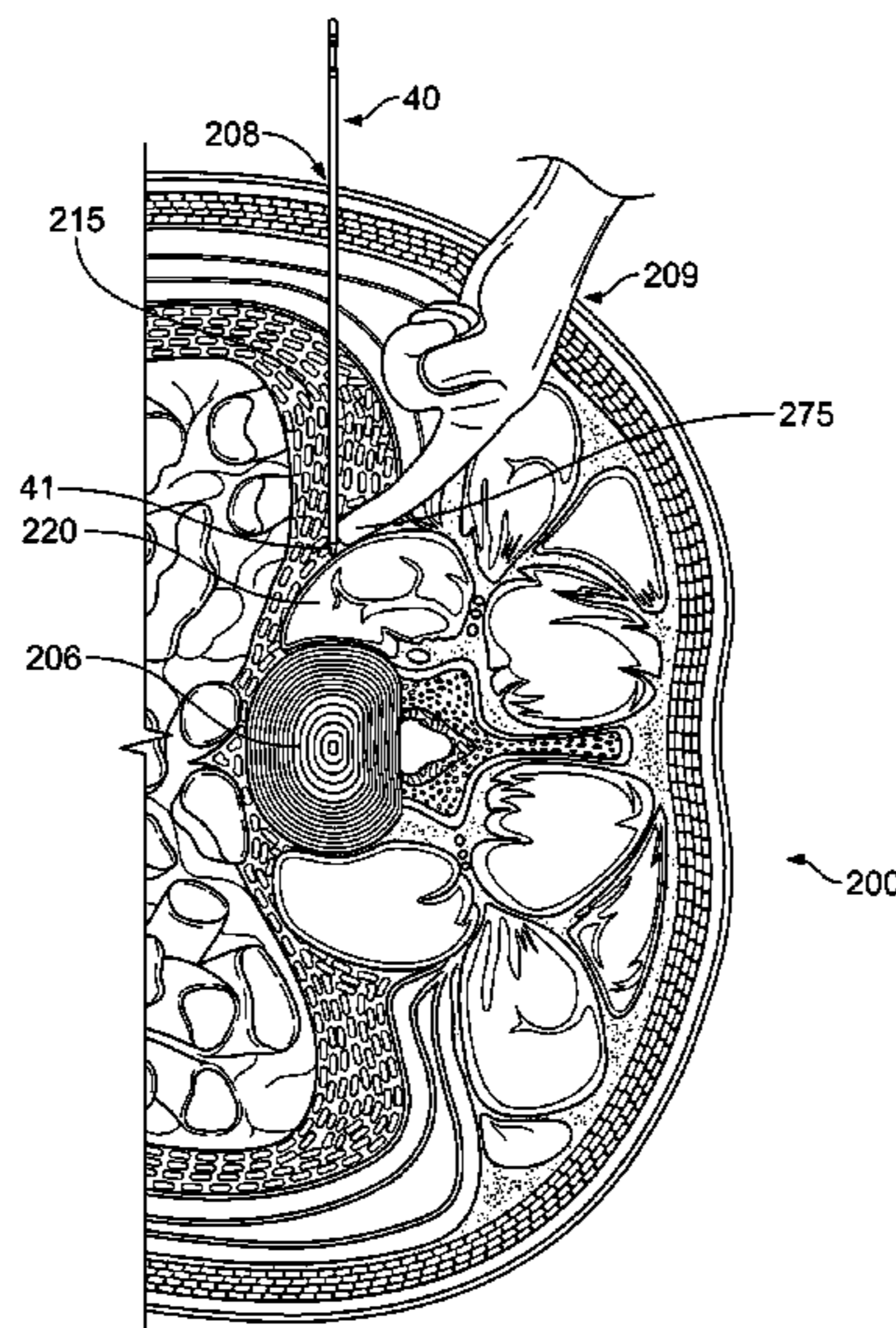
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(57) **ABSTRACT**

A surgical access system including a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor to a surgical target site. Some embodiments of the surgical access system may be particularly suited for establishing an operative corridor to a surgical target site in the spine. Such an operative corridor may be established through the retroperitoneal space and the psoas muscle during a direct lateral, retroperitoneal approach to the spine.

**30 Claims, 50 Drawing Sheets**



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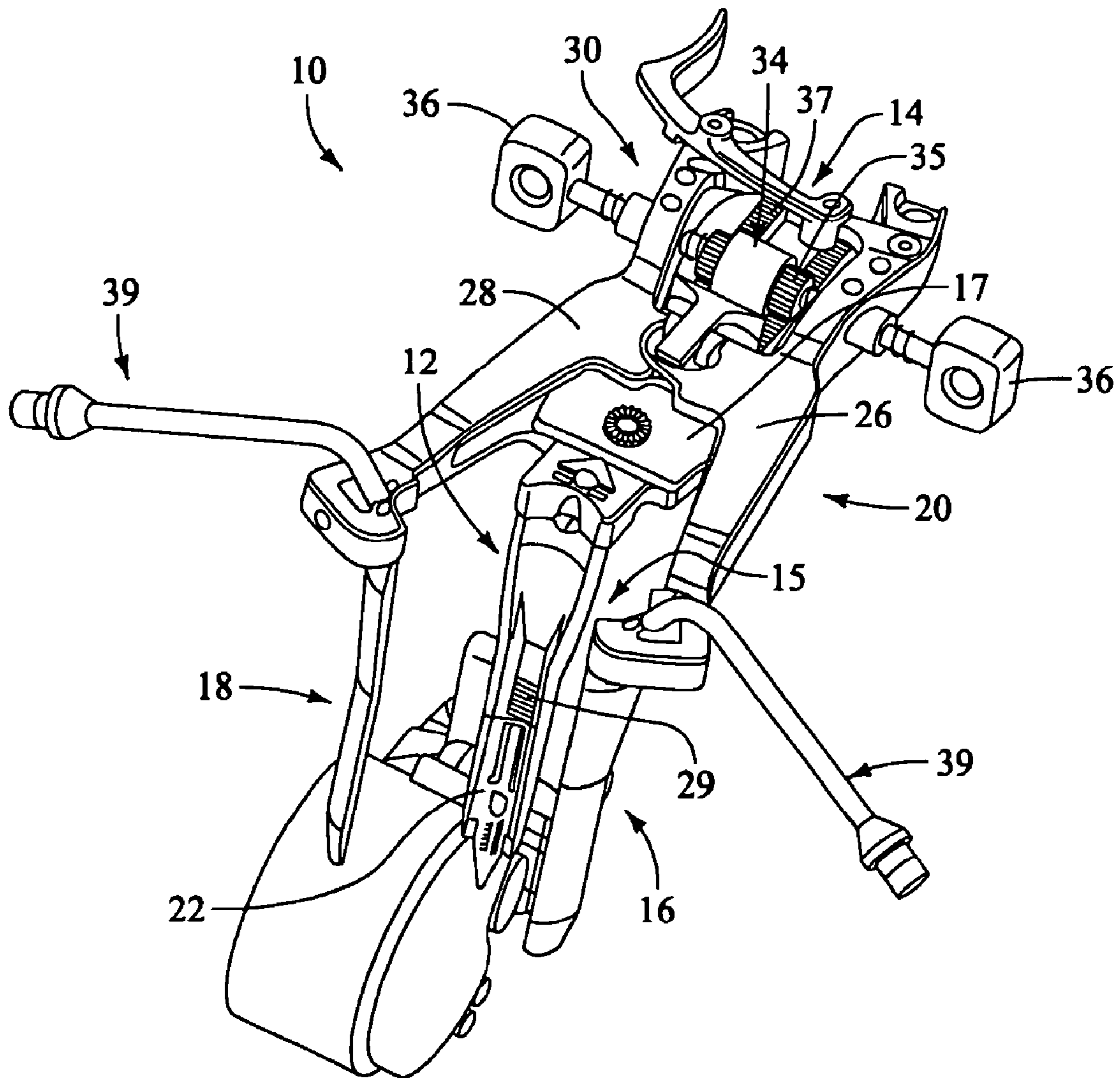


FIG. 1

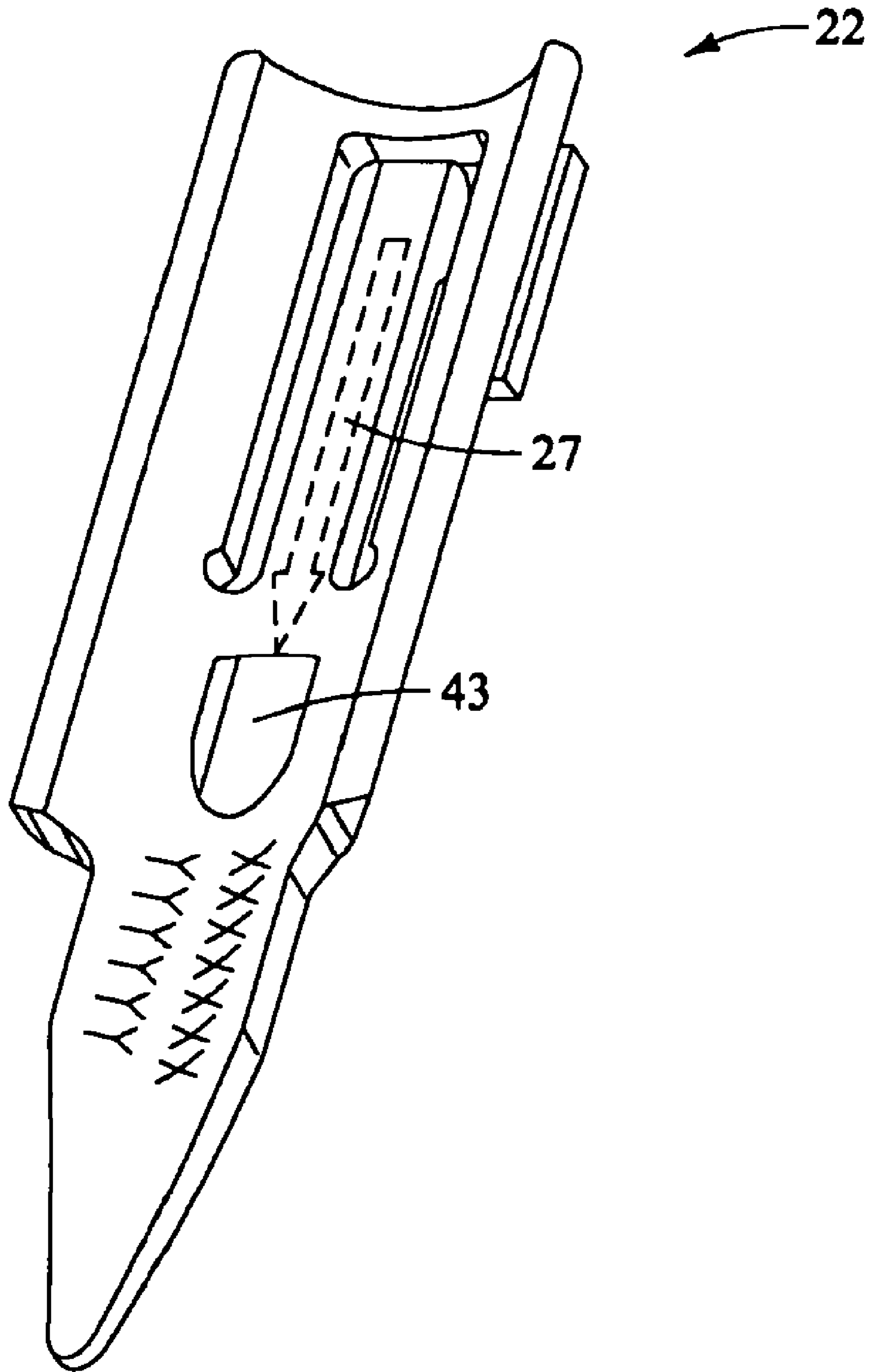


FIG. 2

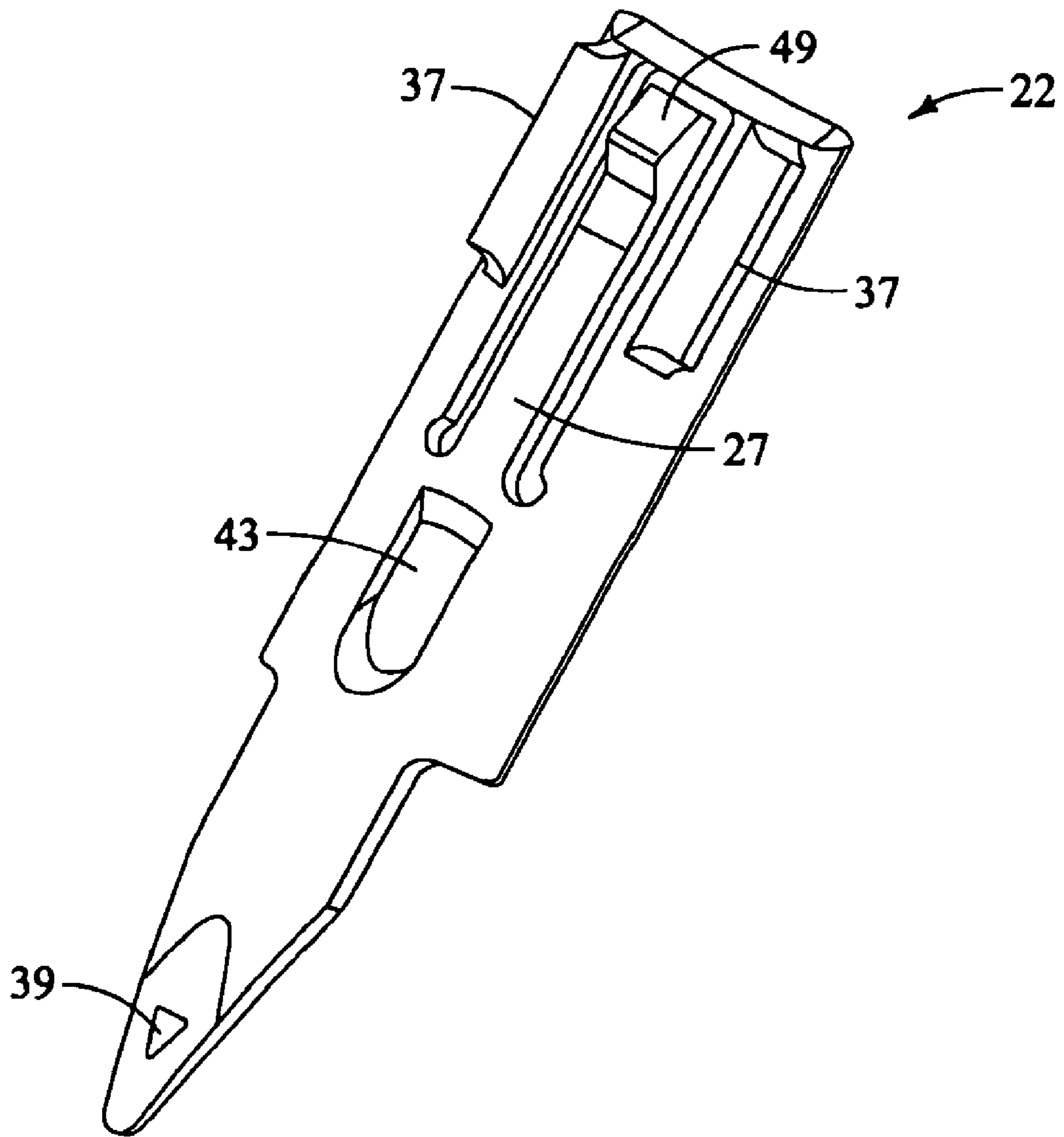


FIG. 3



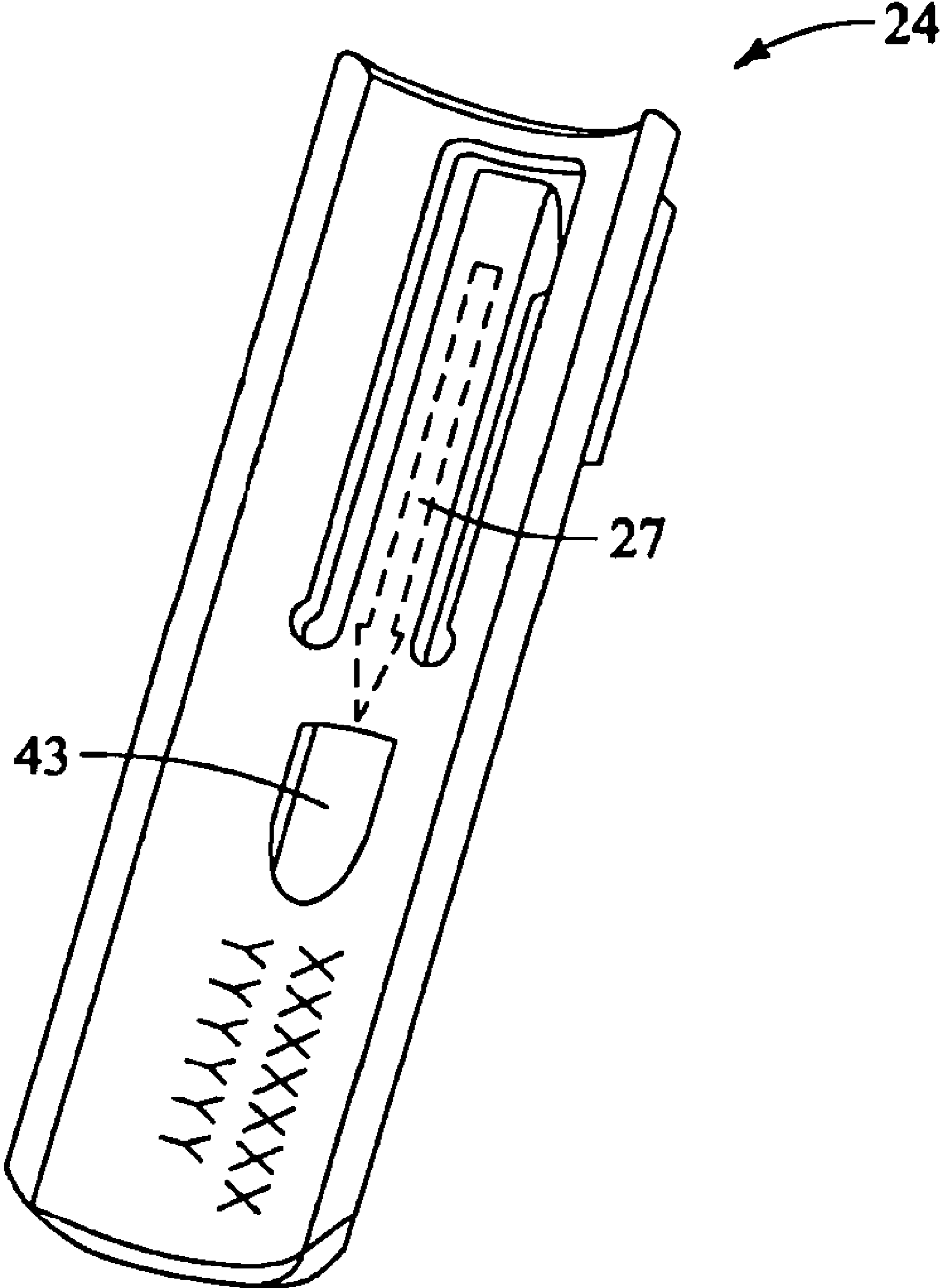


FIG. 4

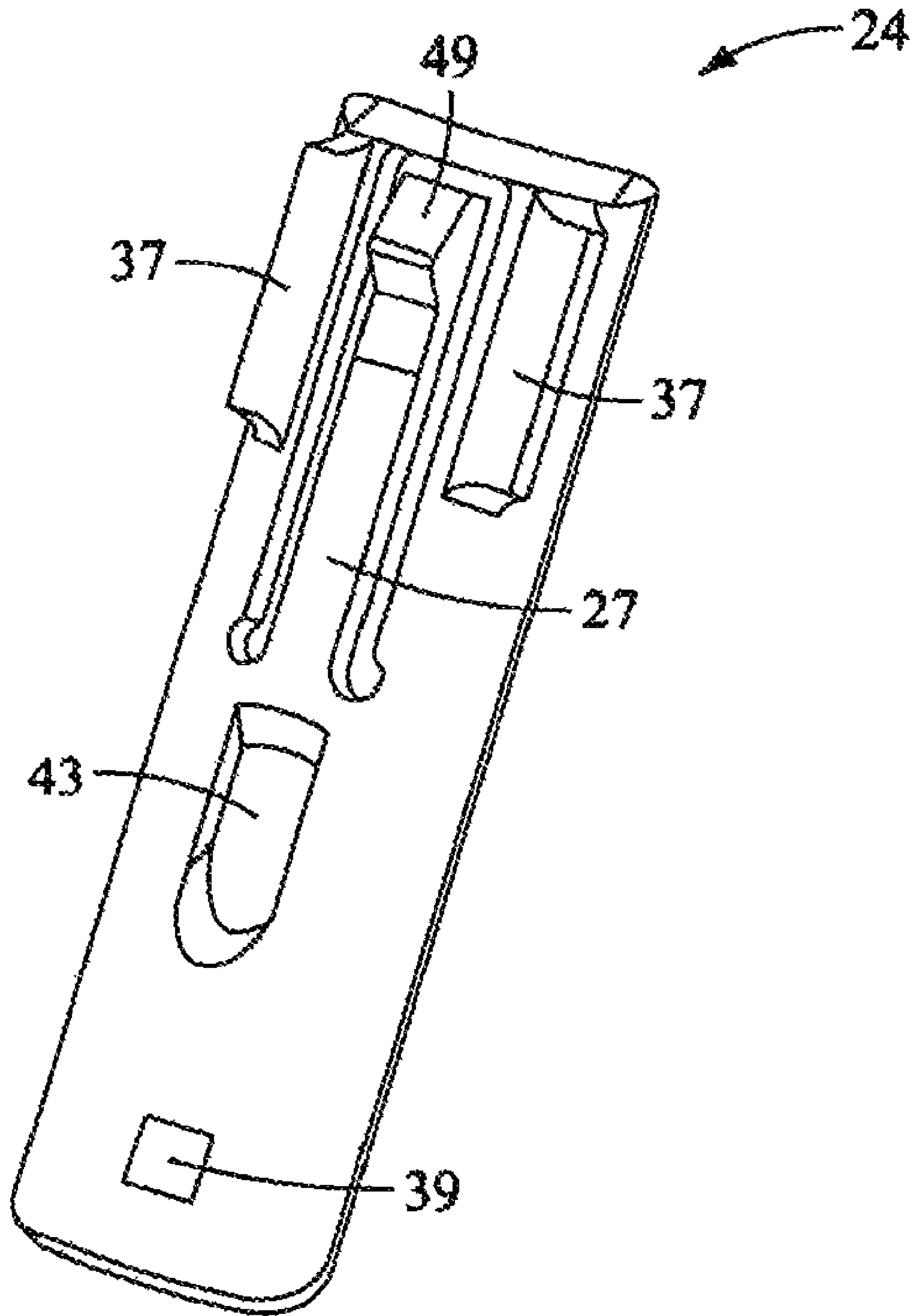


FIG. 5

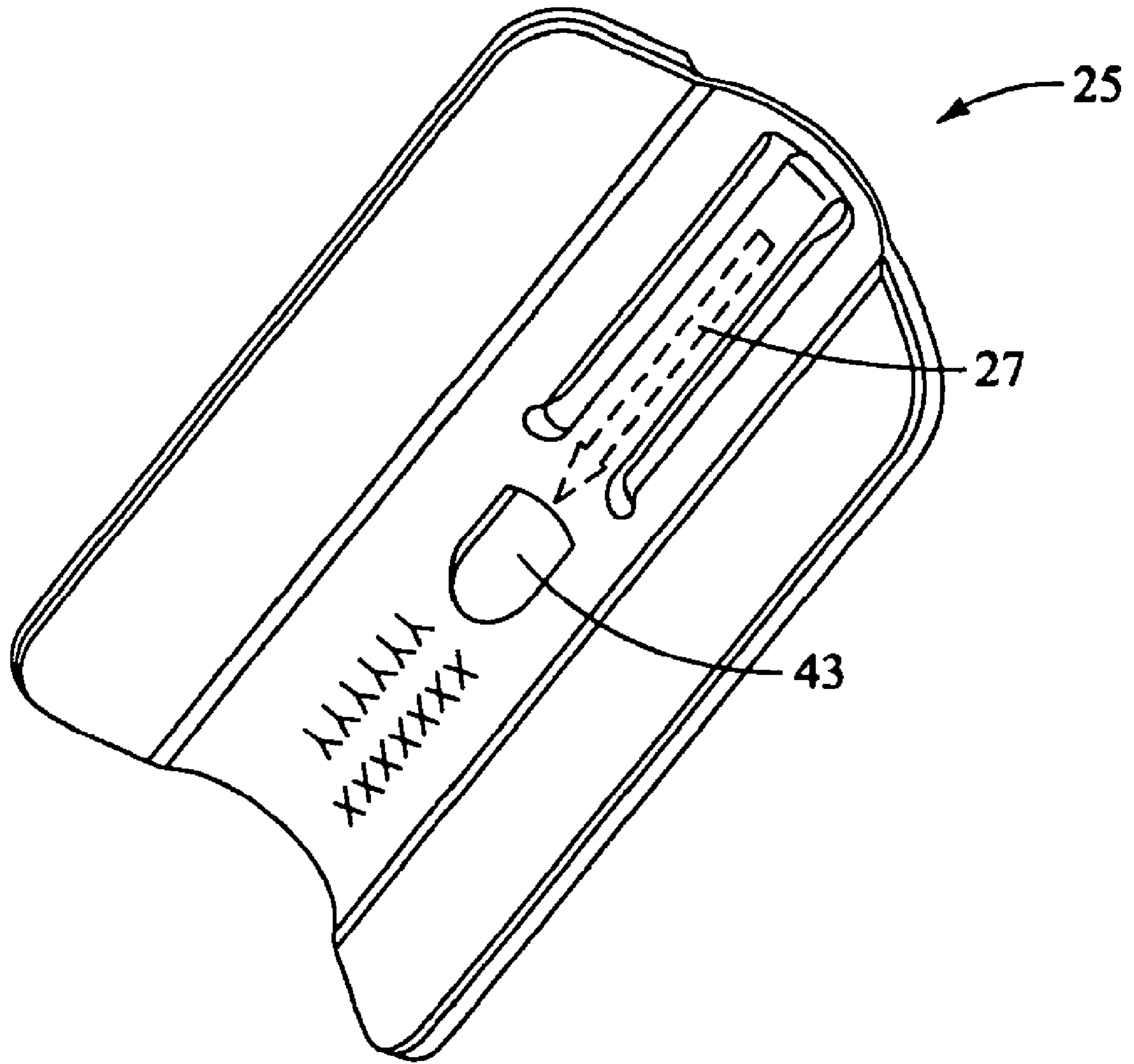


FIG. 6

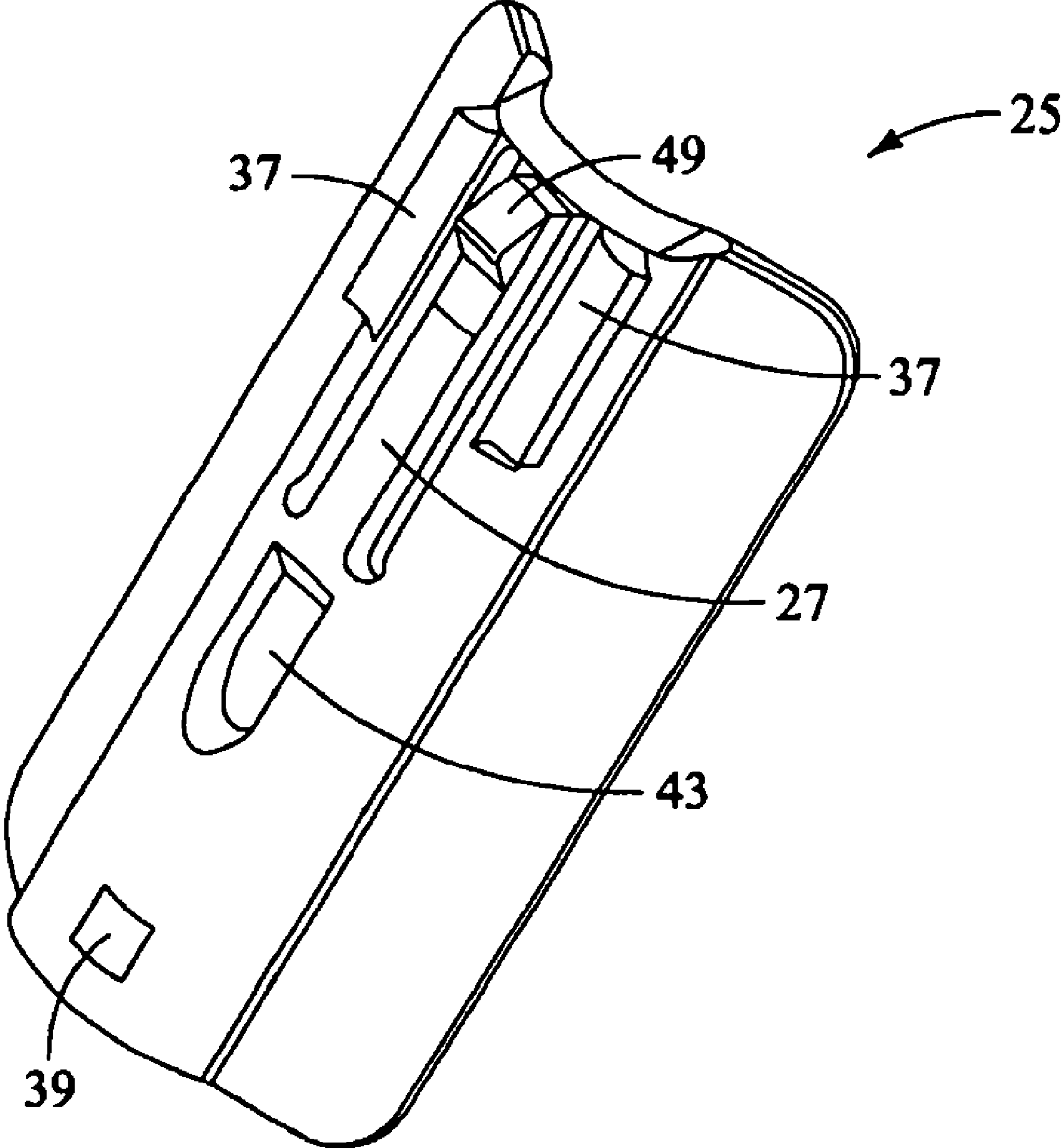


FIG. 7

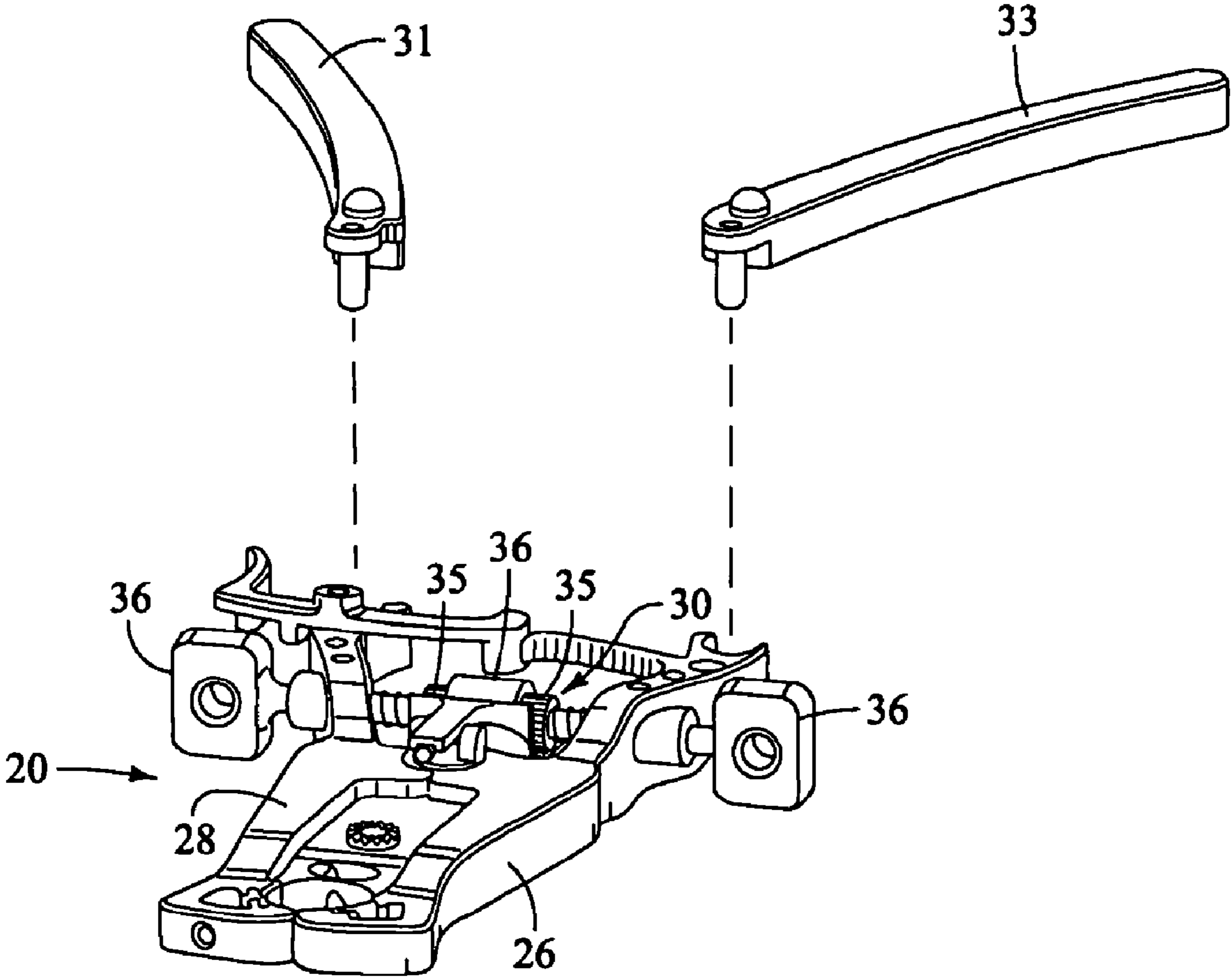


FIG. 8

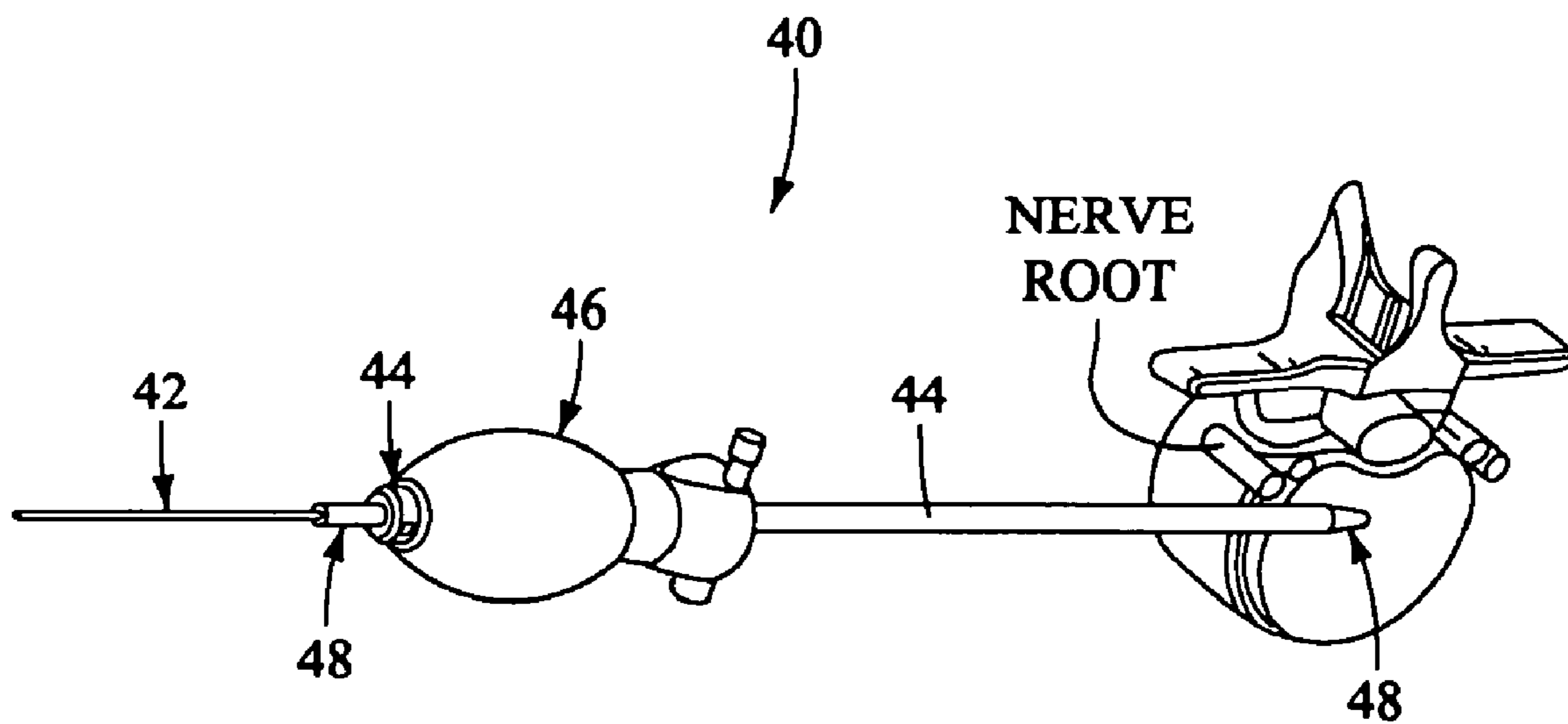


FIG. 9

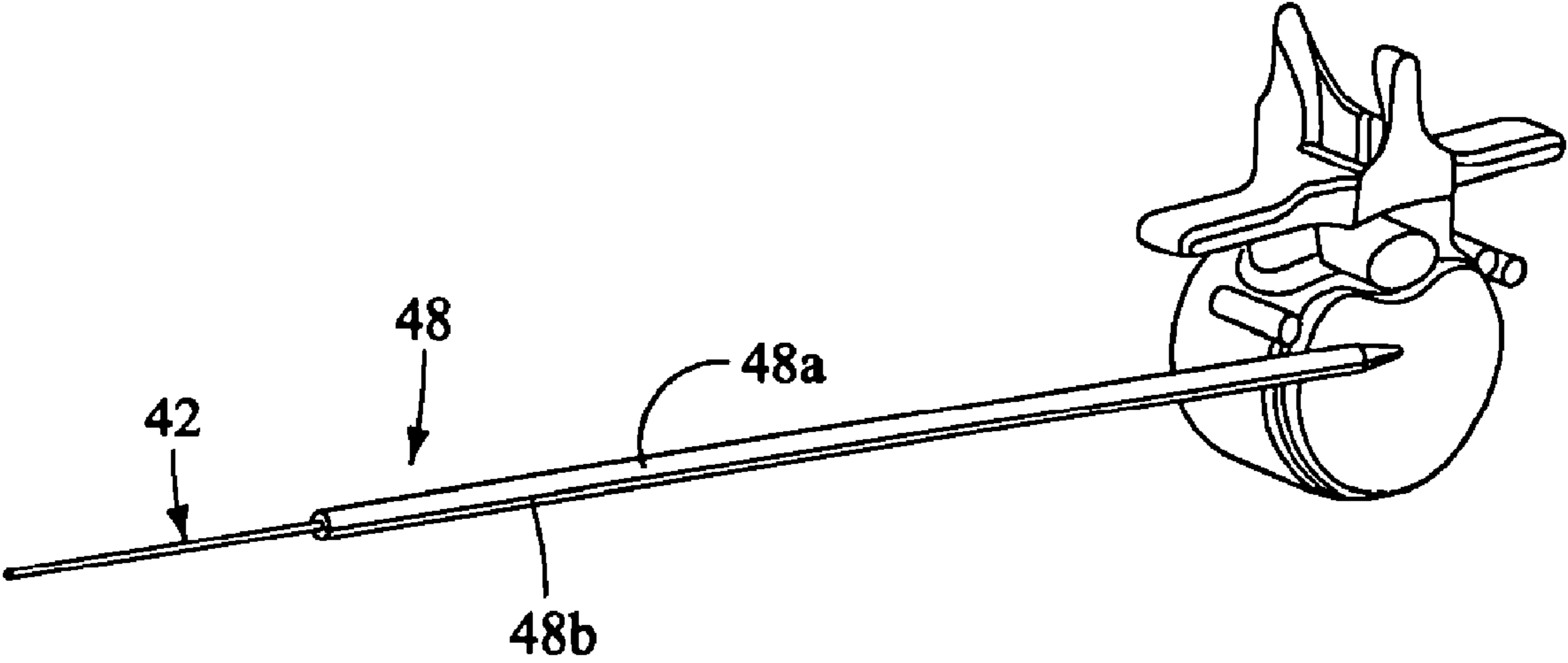


FIG. 10

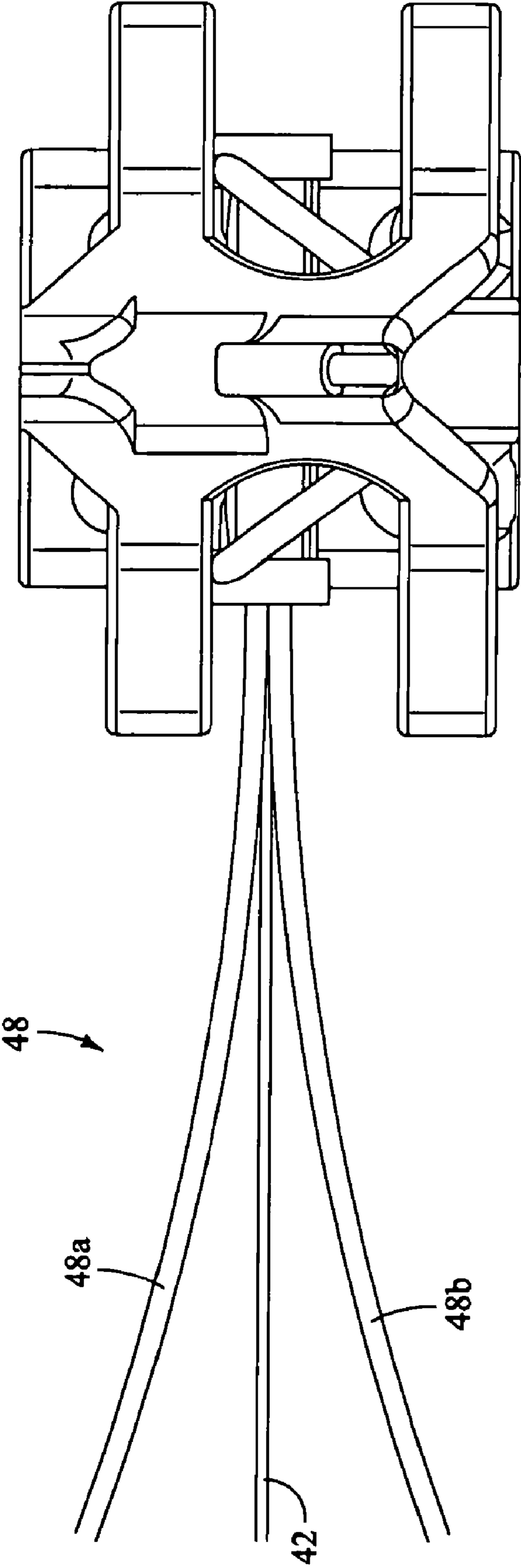


FIG. 11



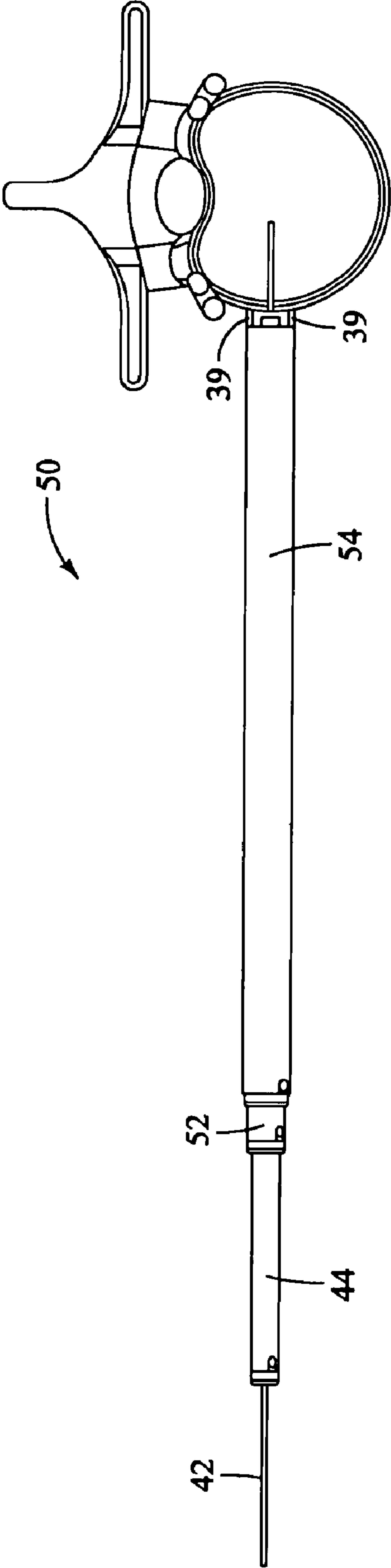


FIG. 12

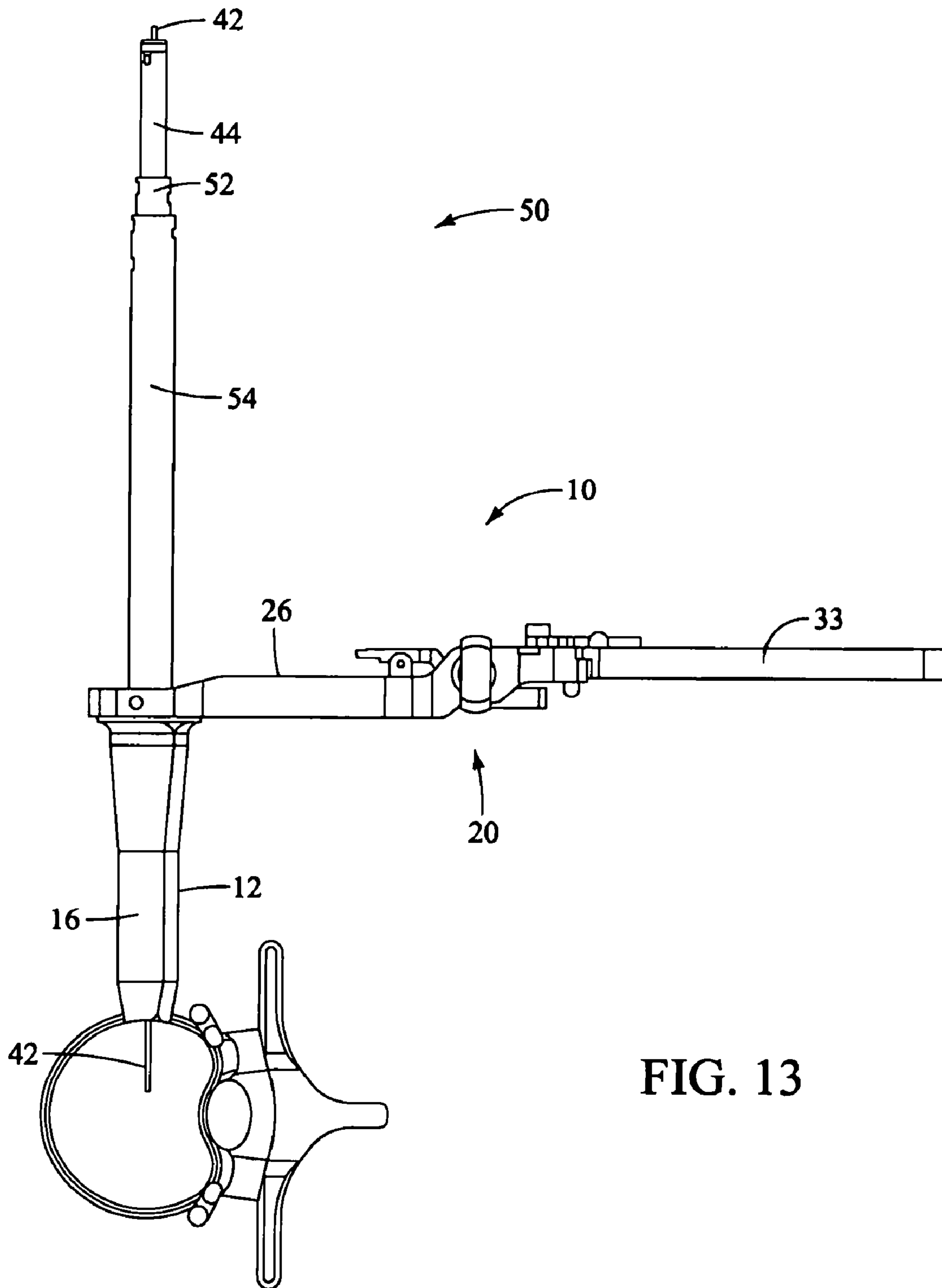


FIG. 13

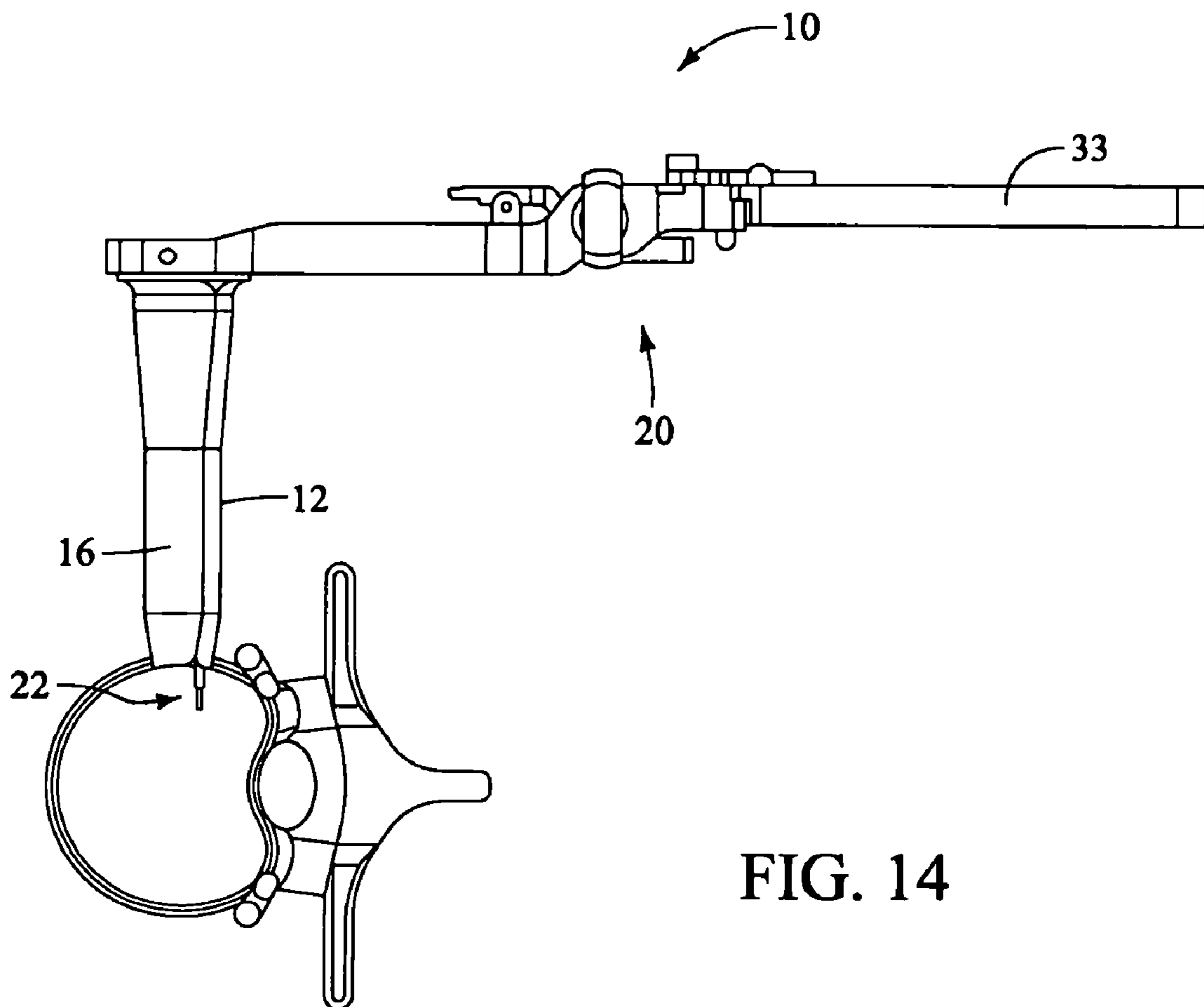


FIG. 14



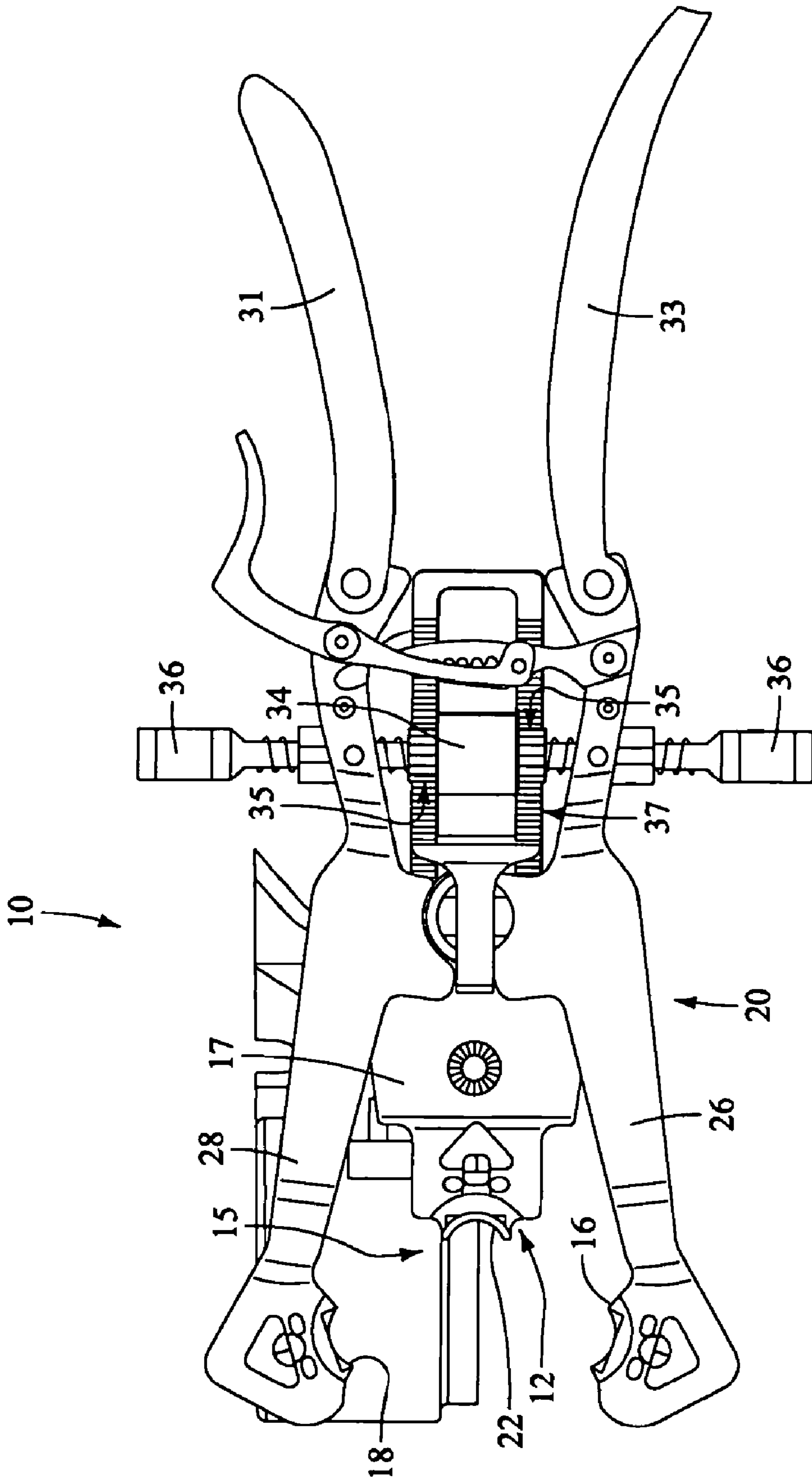


FIG. 16

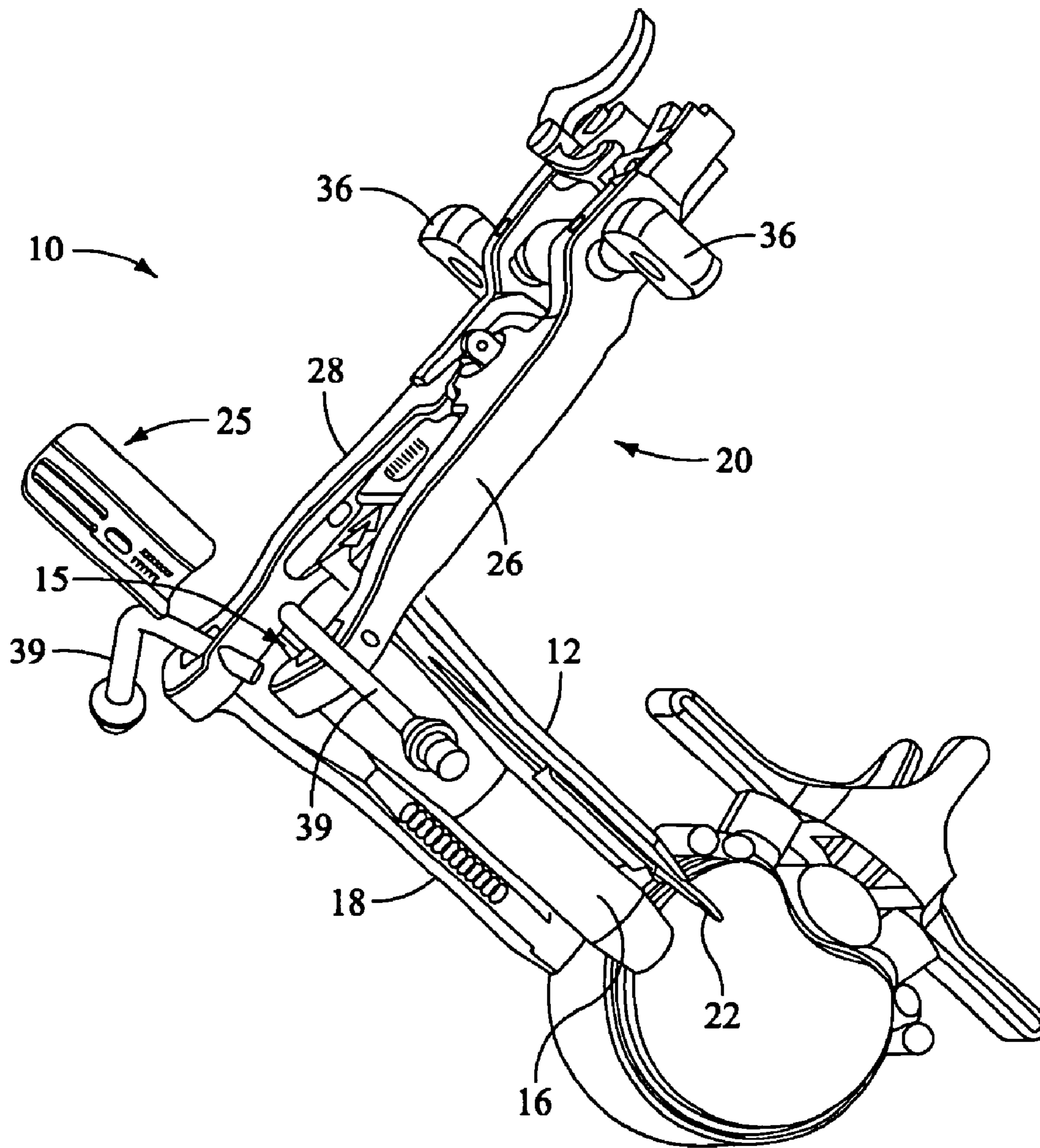


FIG. 17

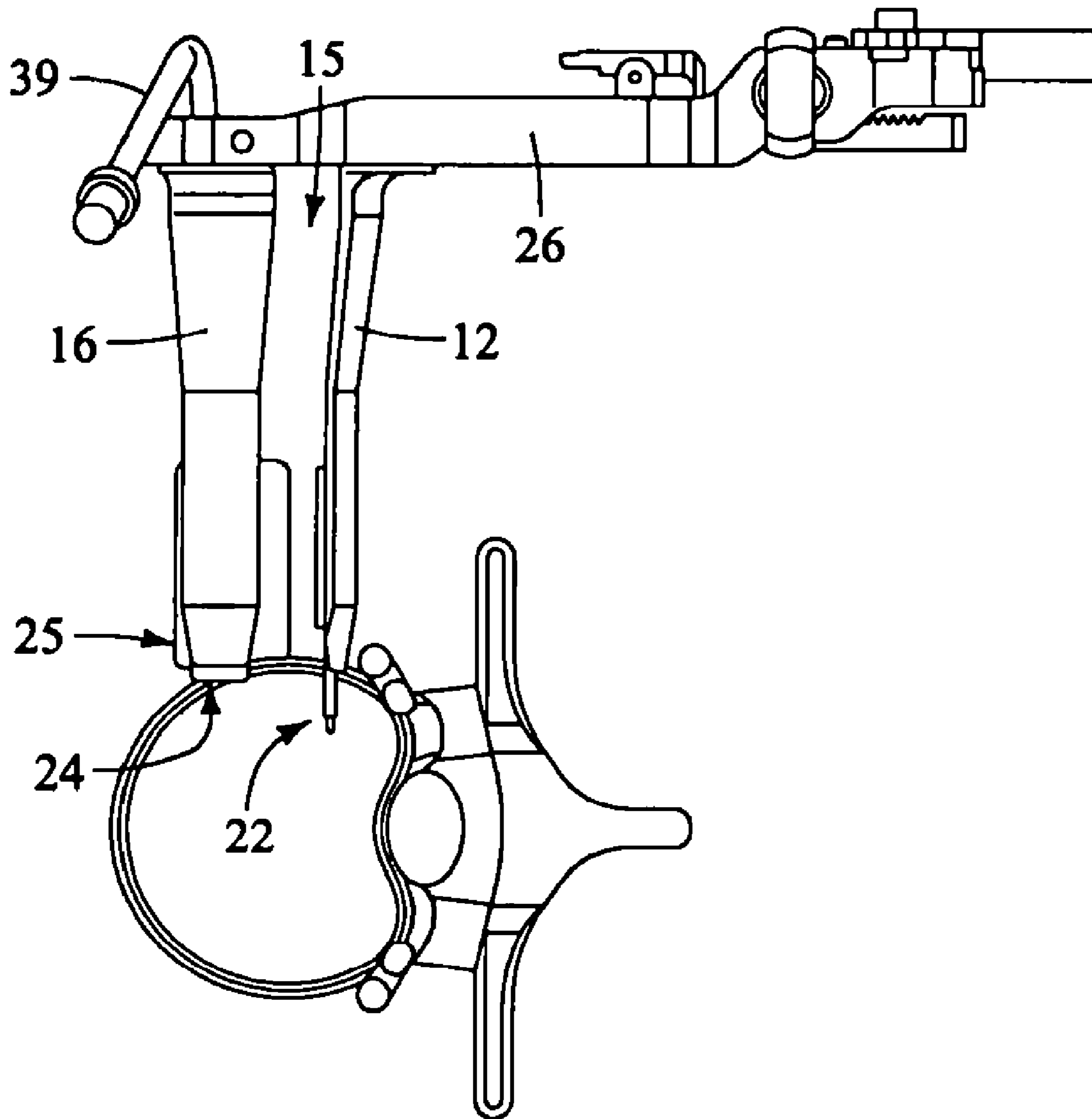


FIG. 18

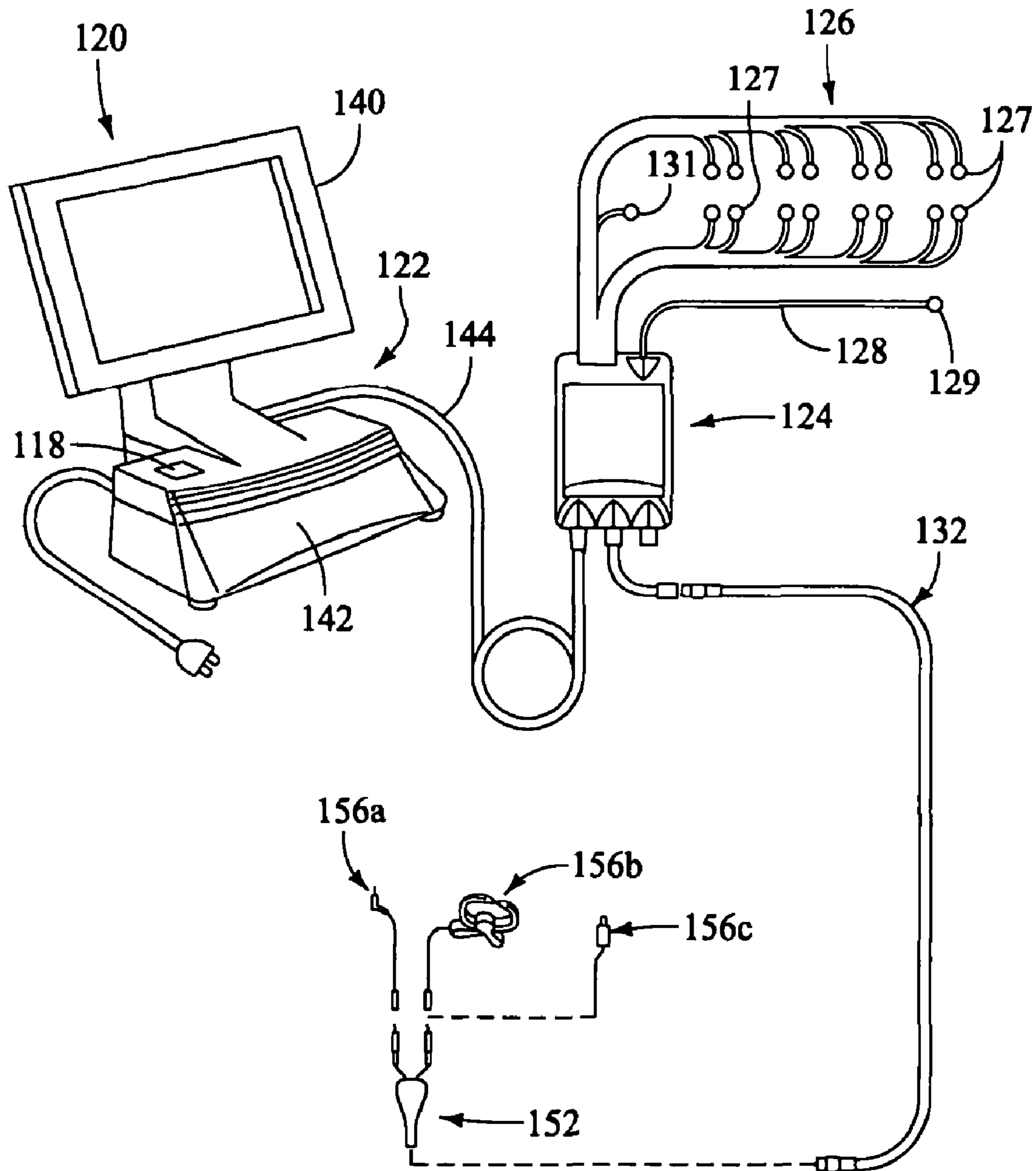


FIG. 19



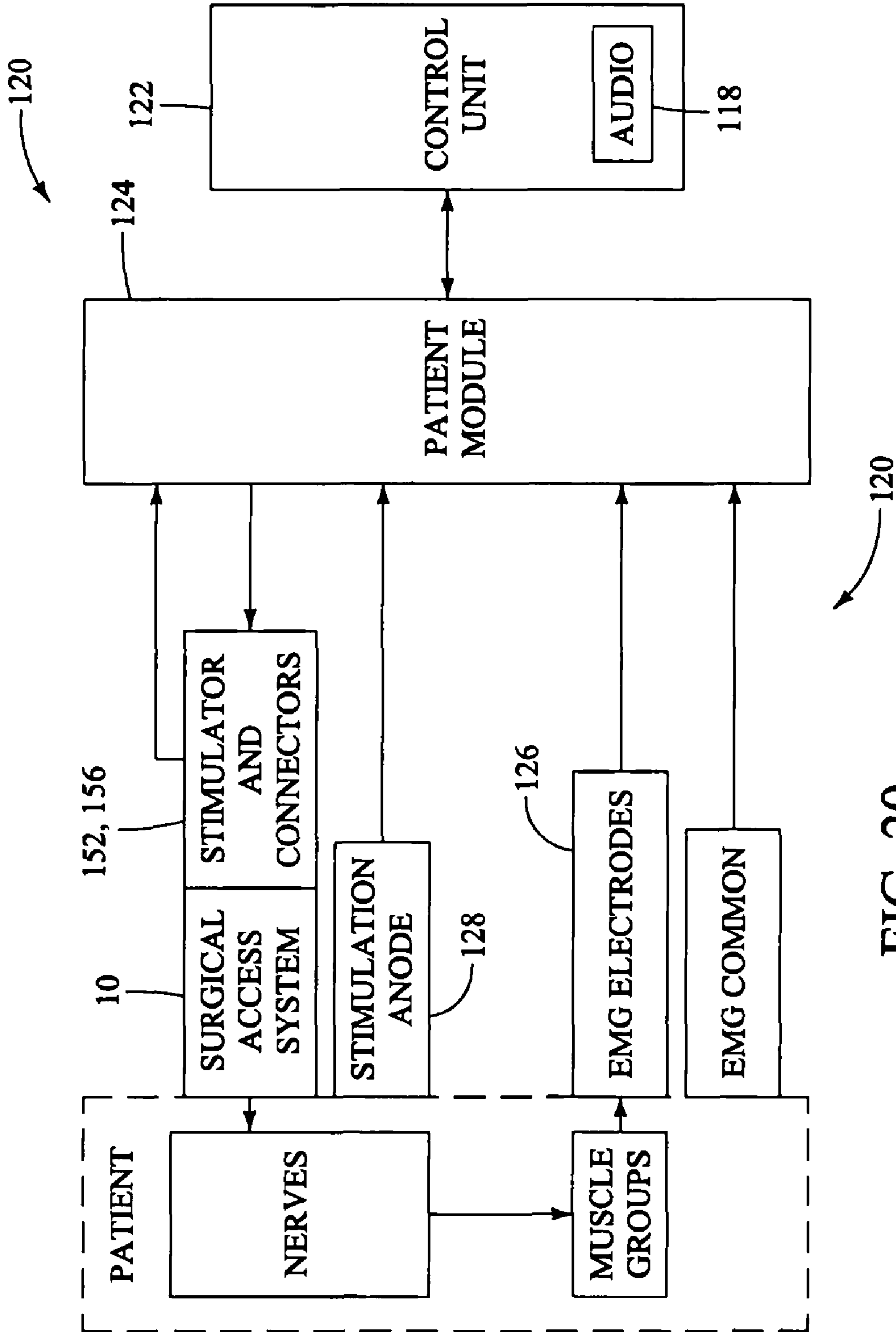


FIG. 20

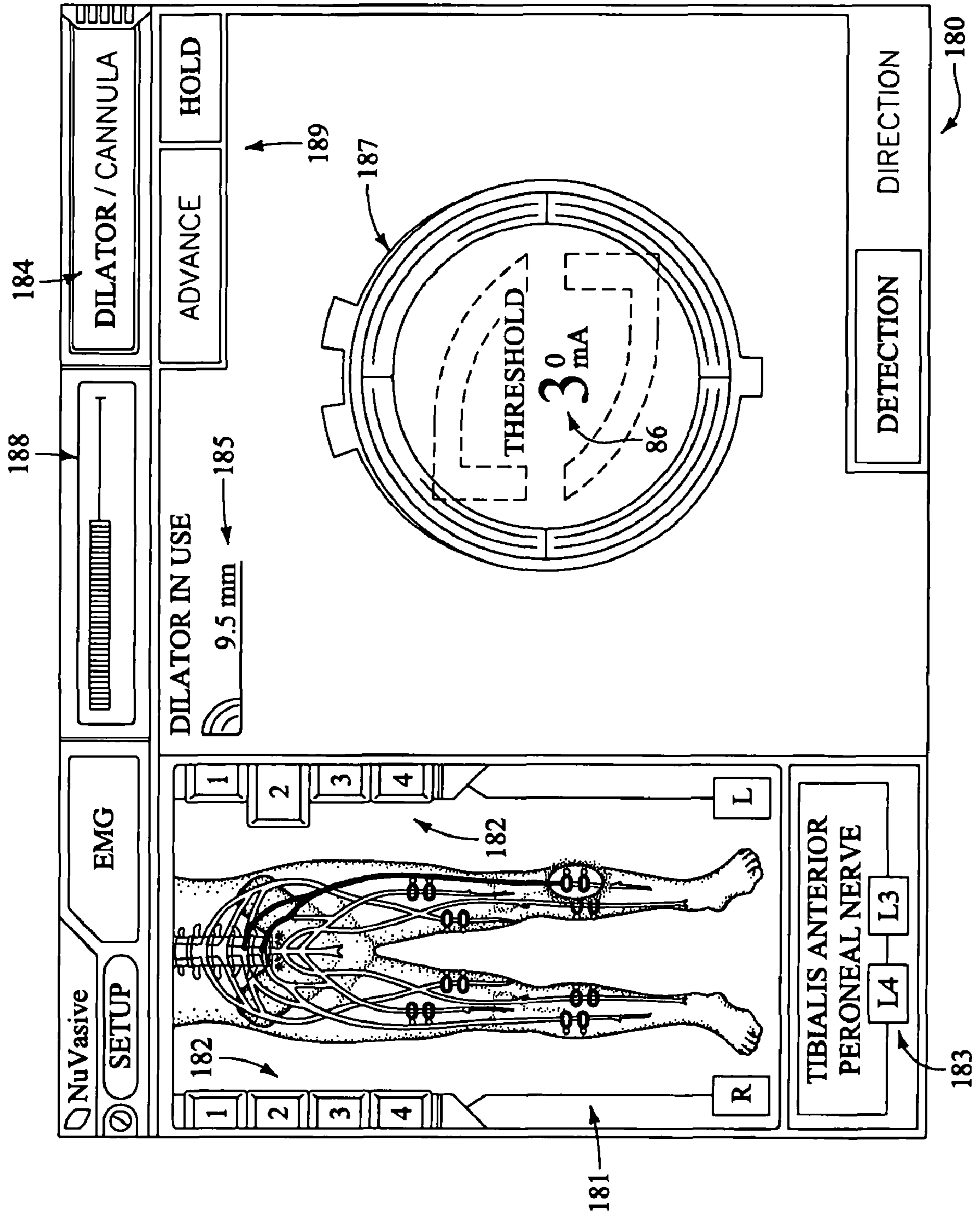


FIG. 21

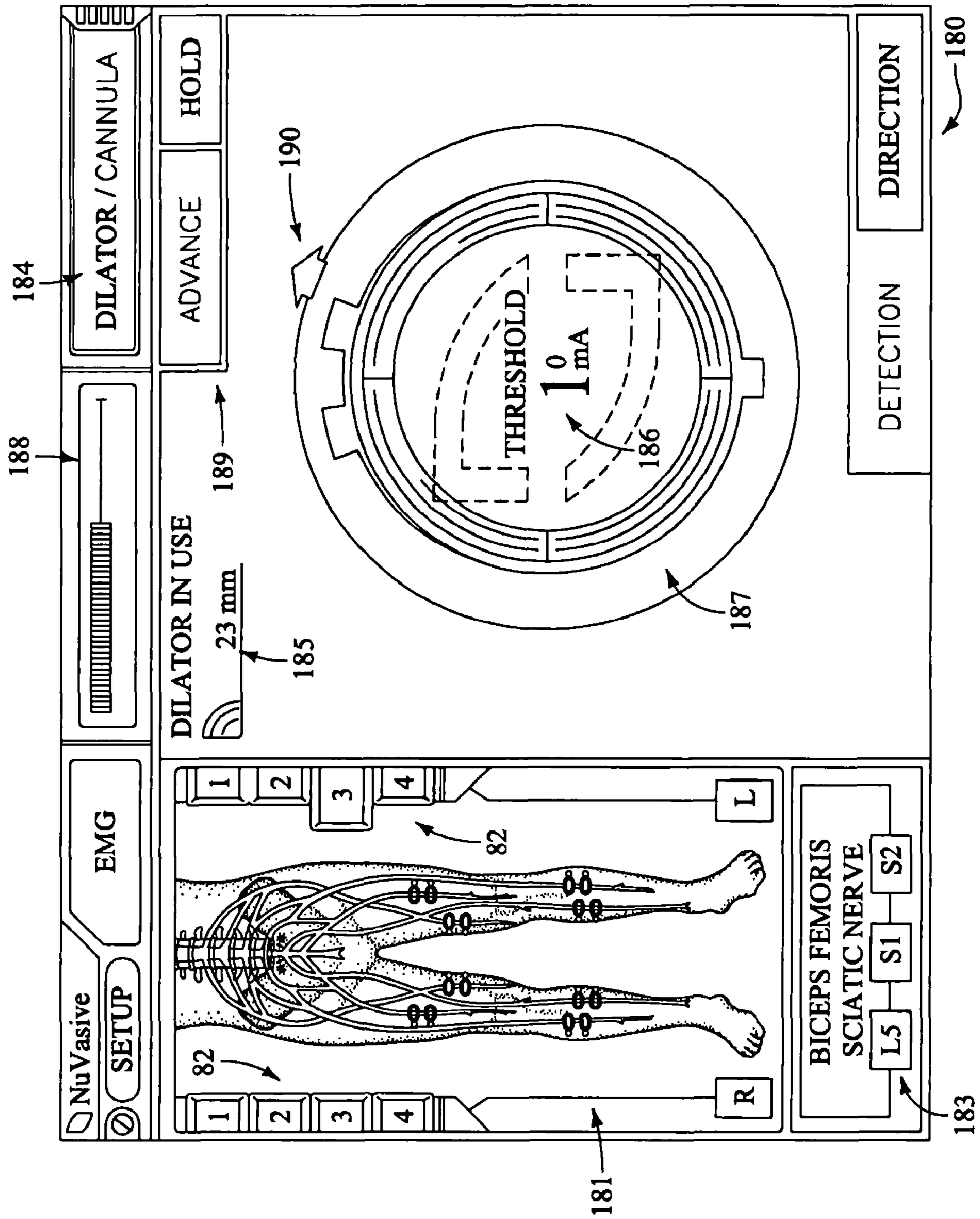


FIG. 22

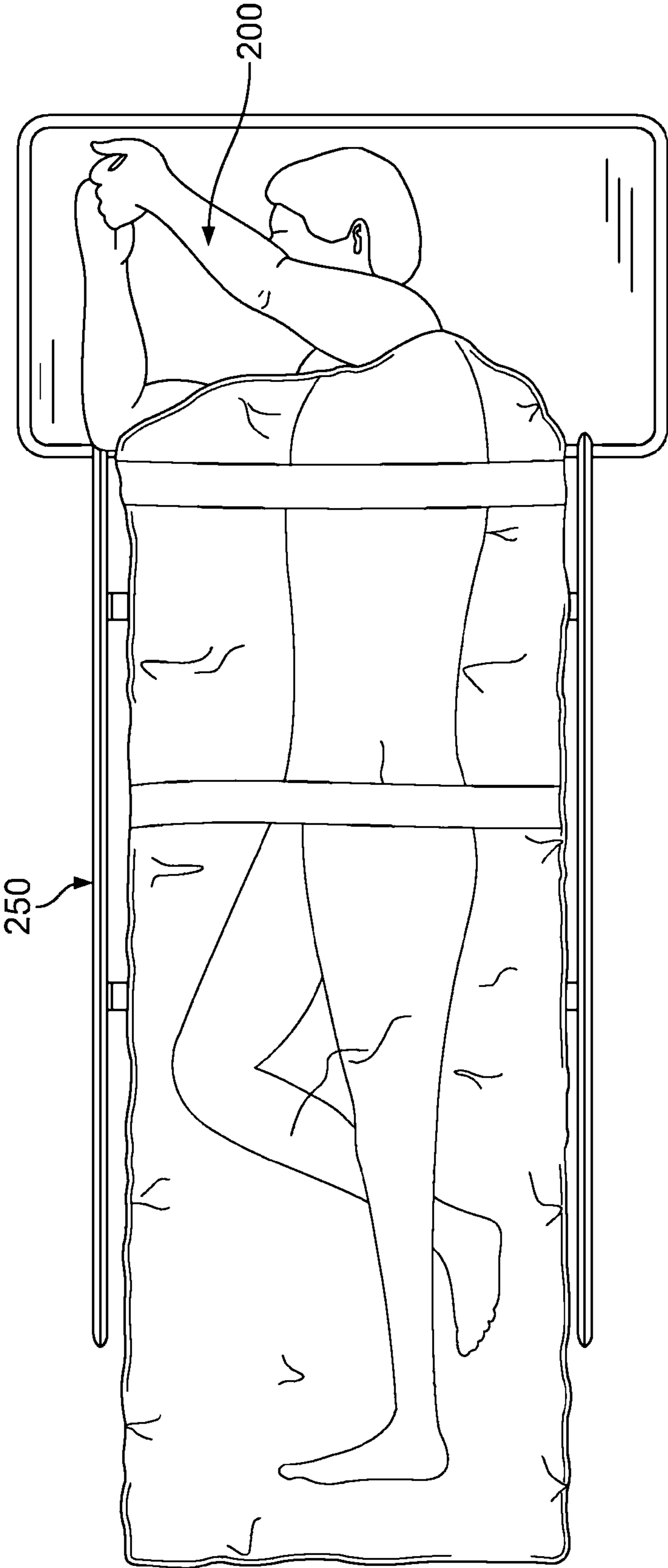


FIG. 23

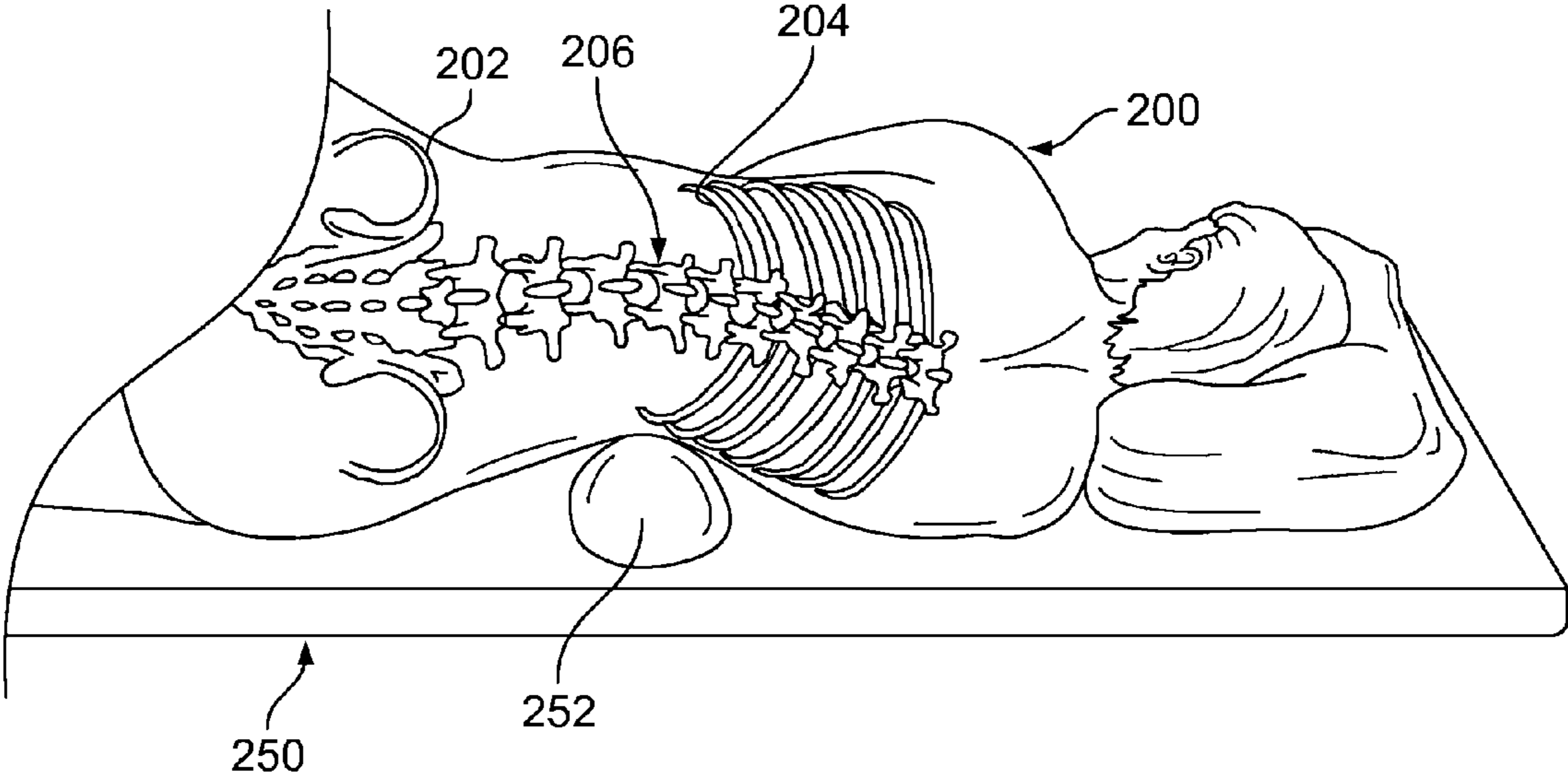


FIG. 24



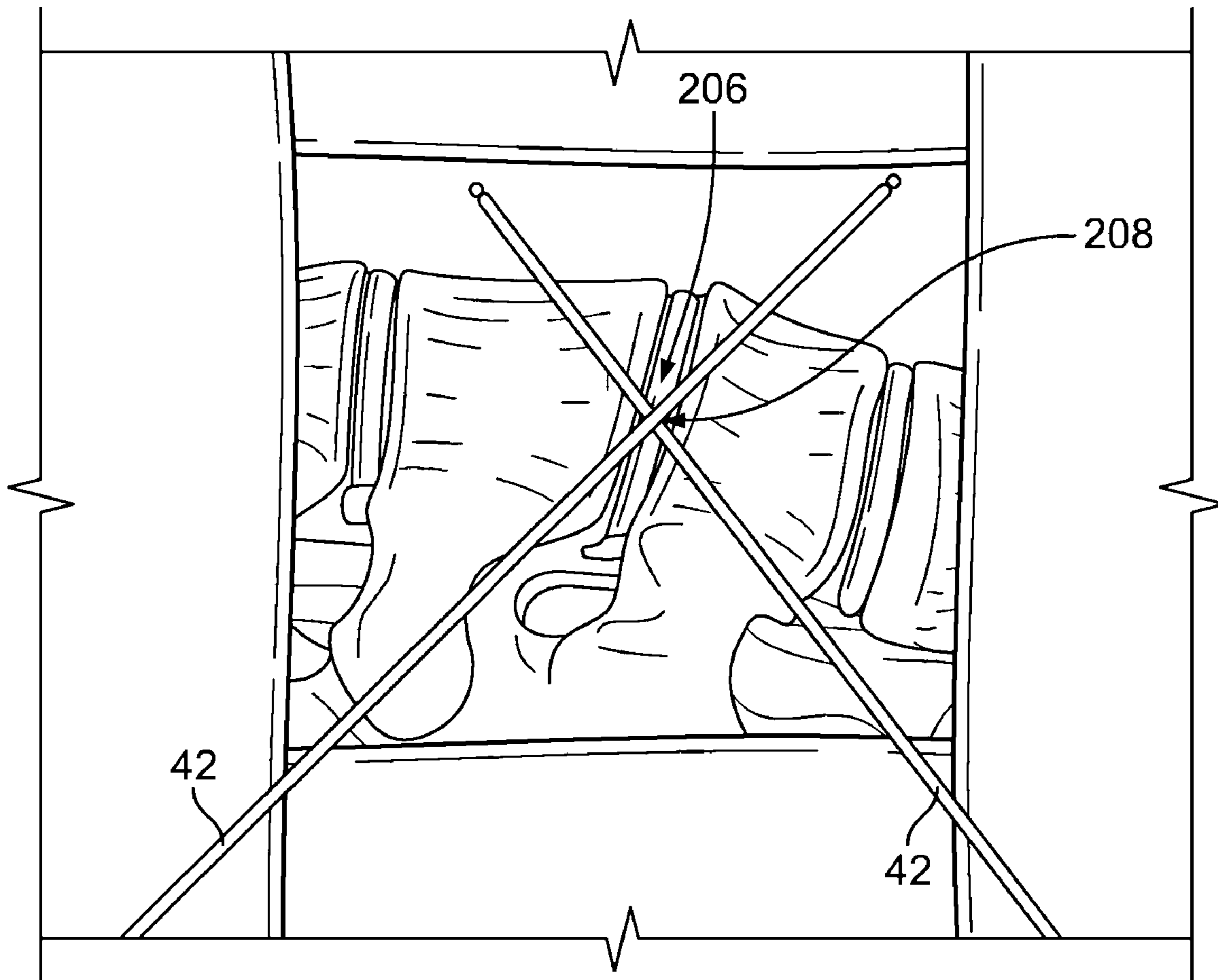


FIG. 26

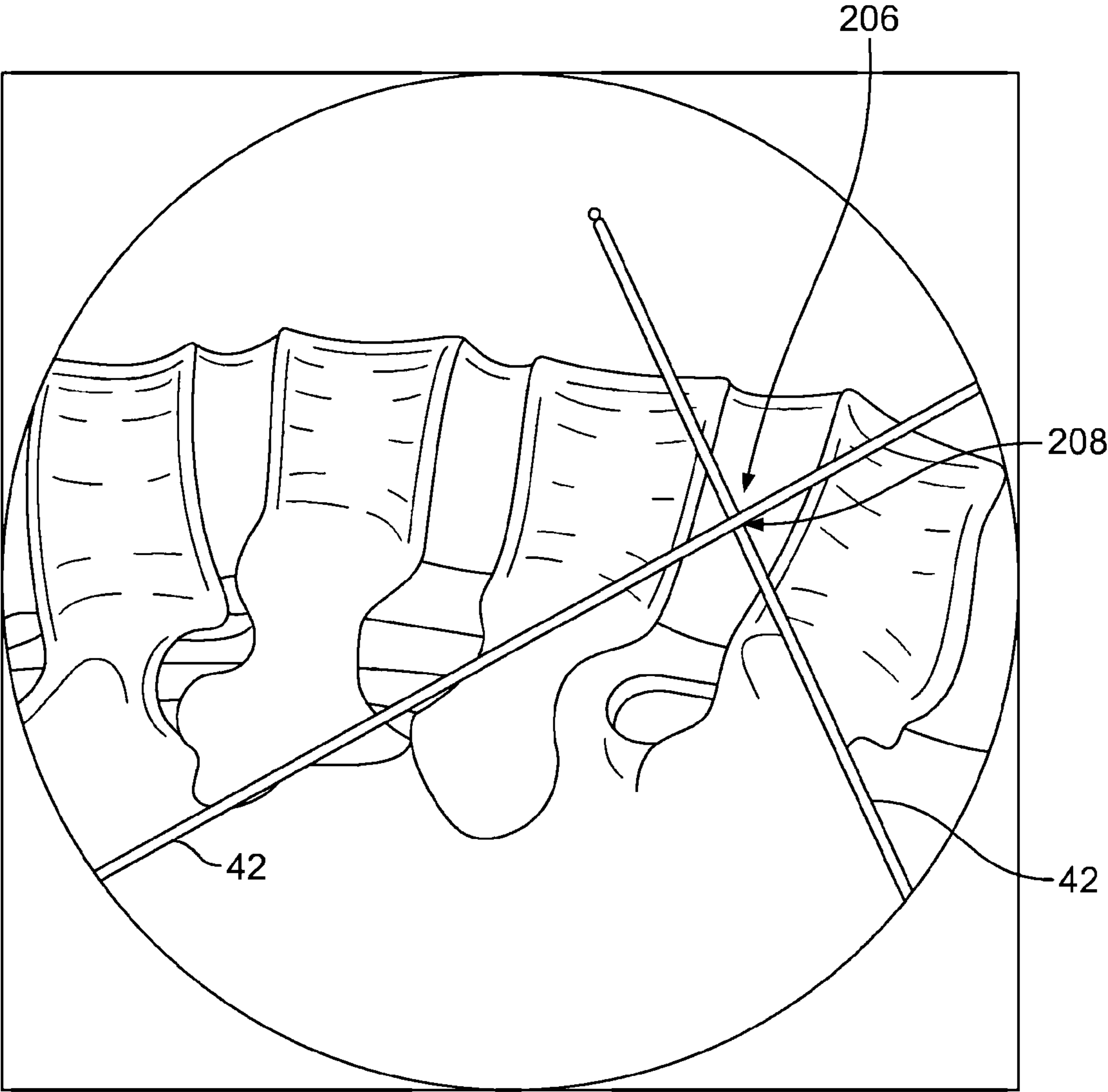


FIG. 27



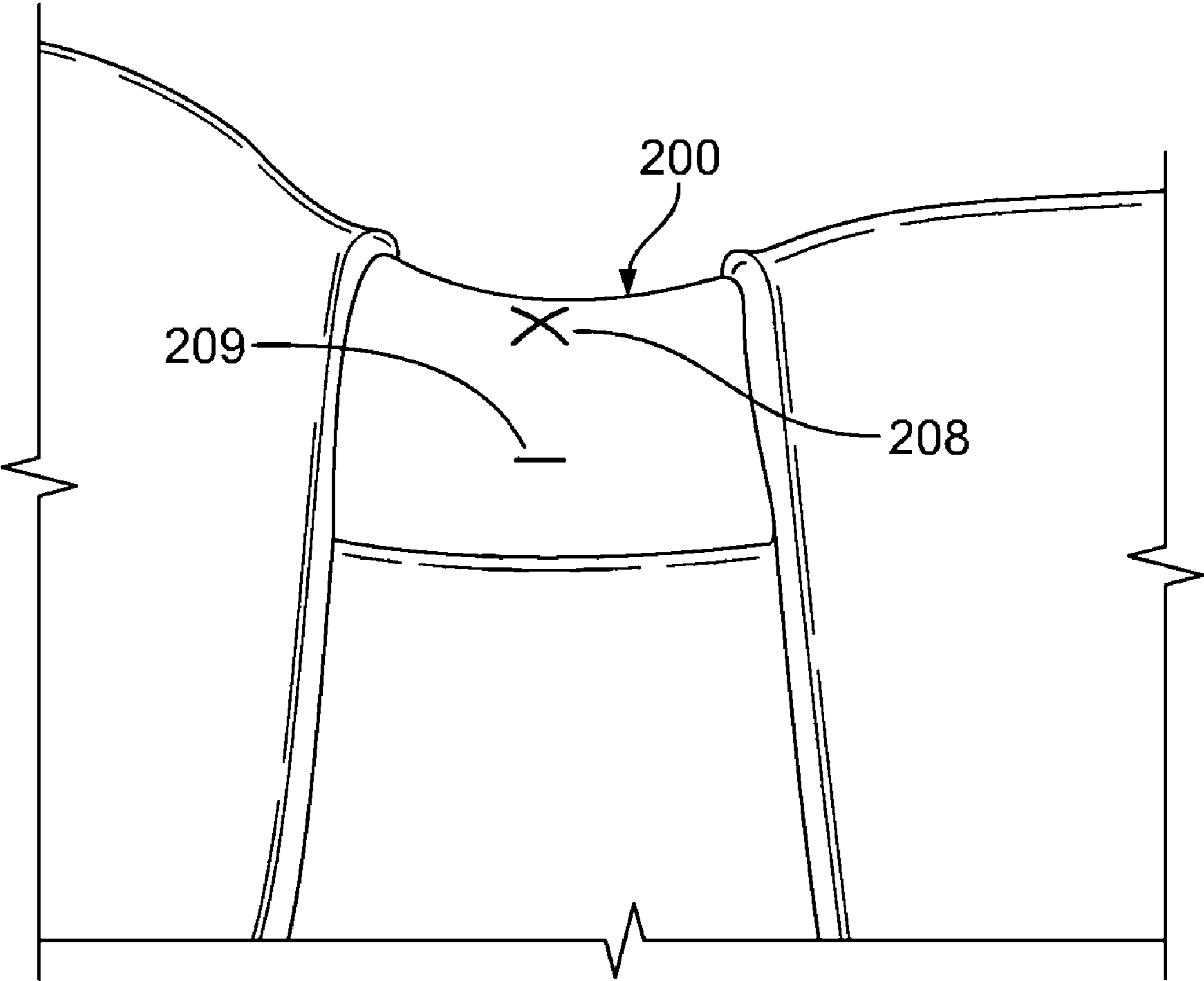
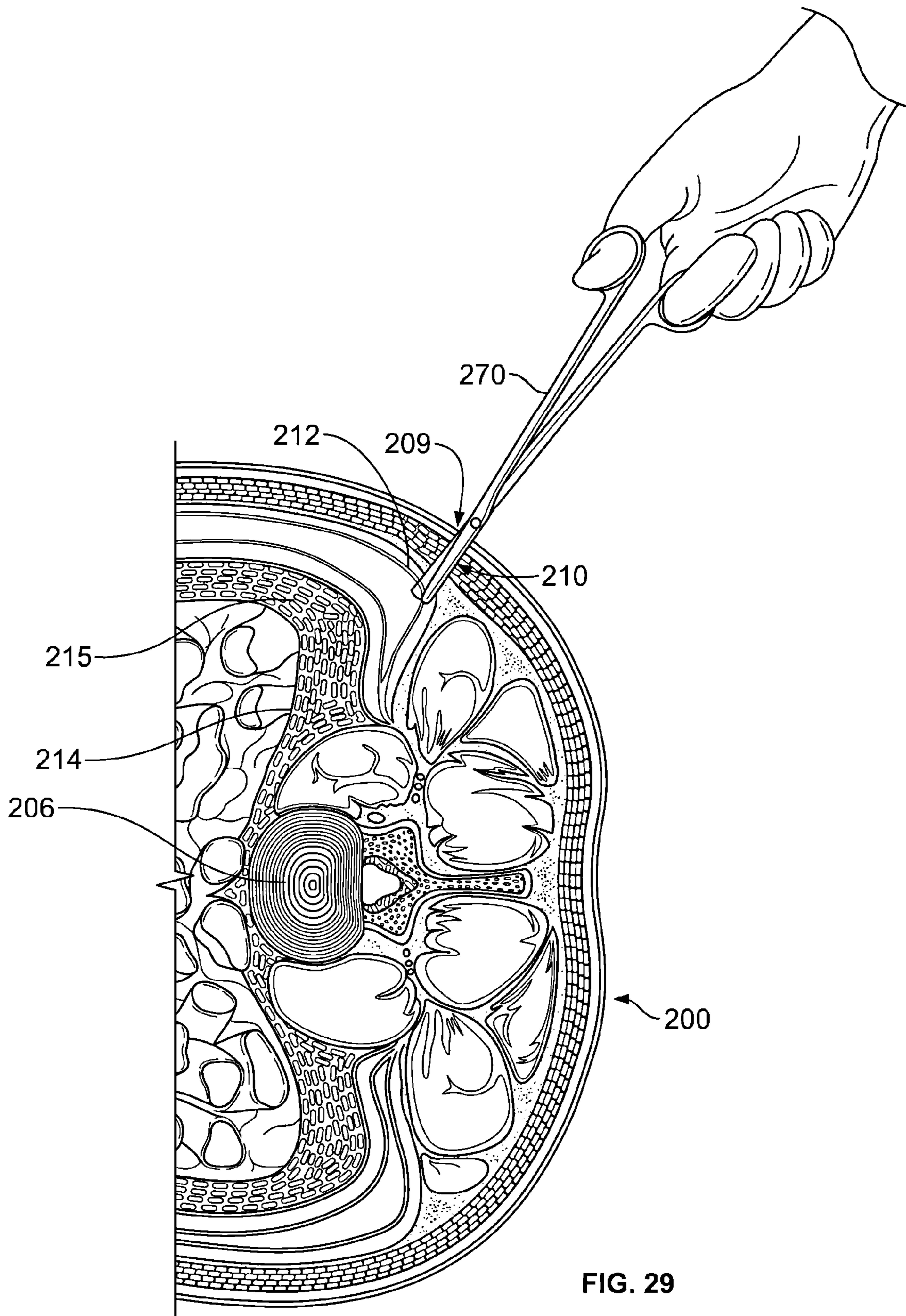


FIG. 28



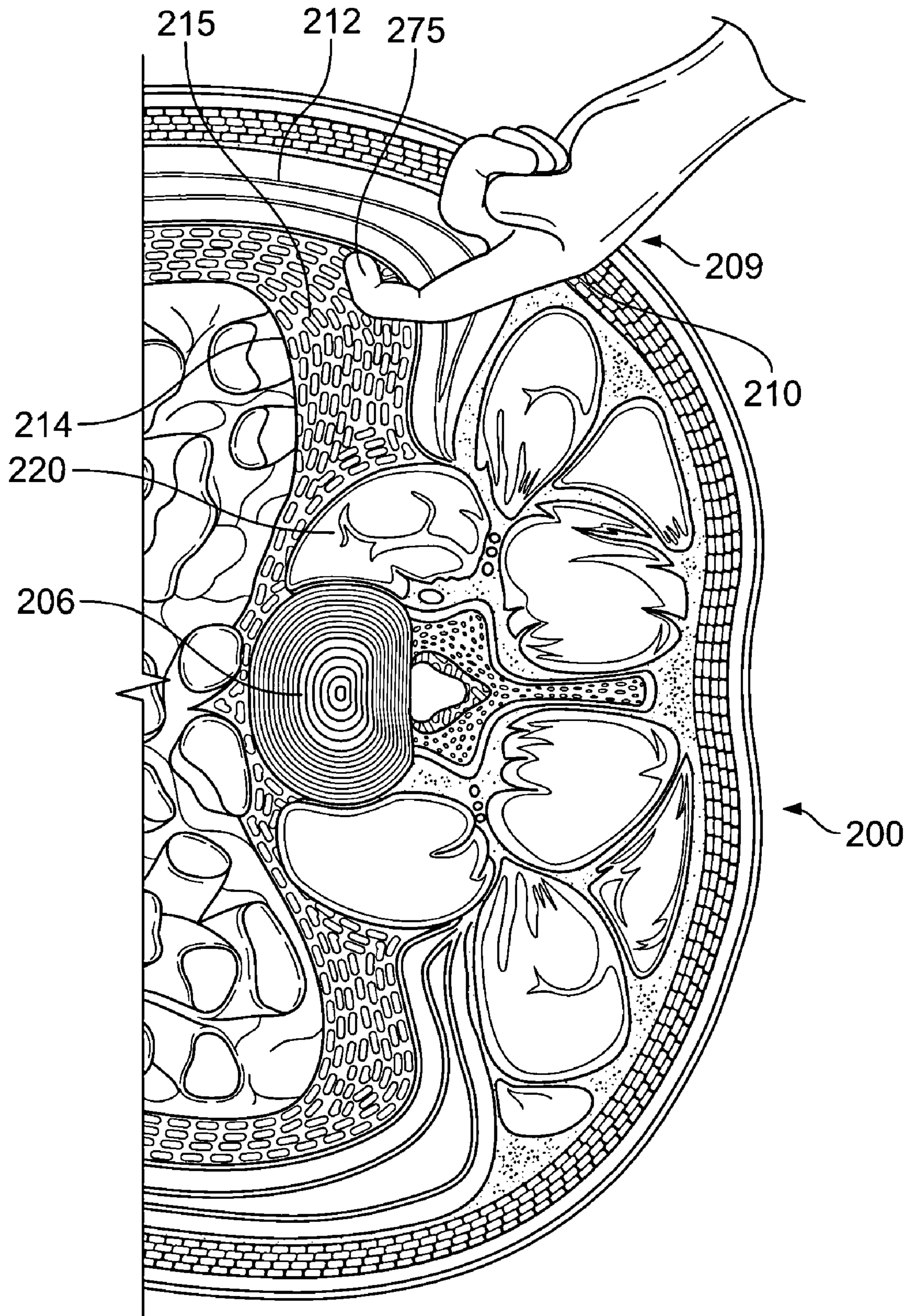


FIG. 30

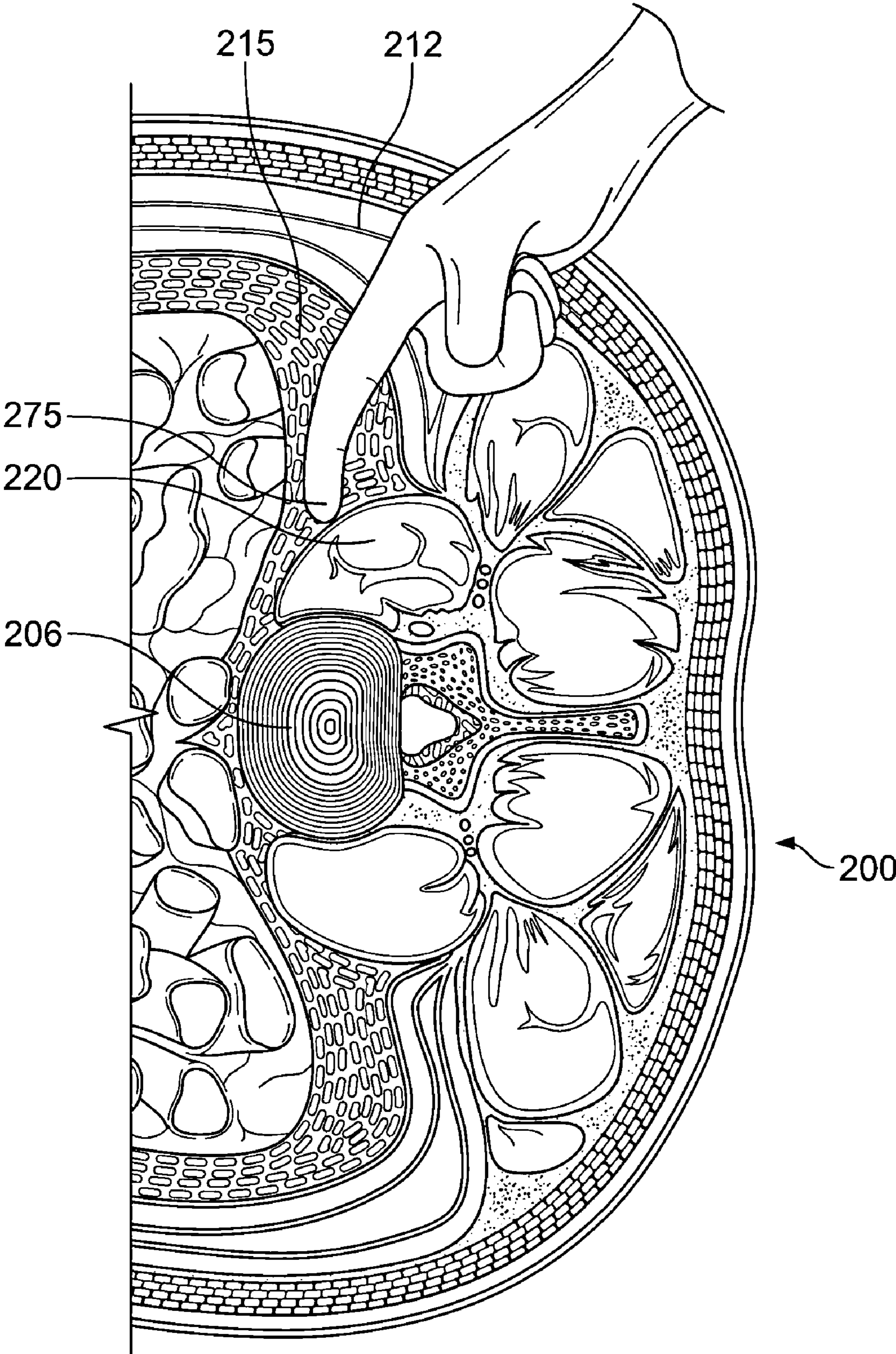


FIG. 31

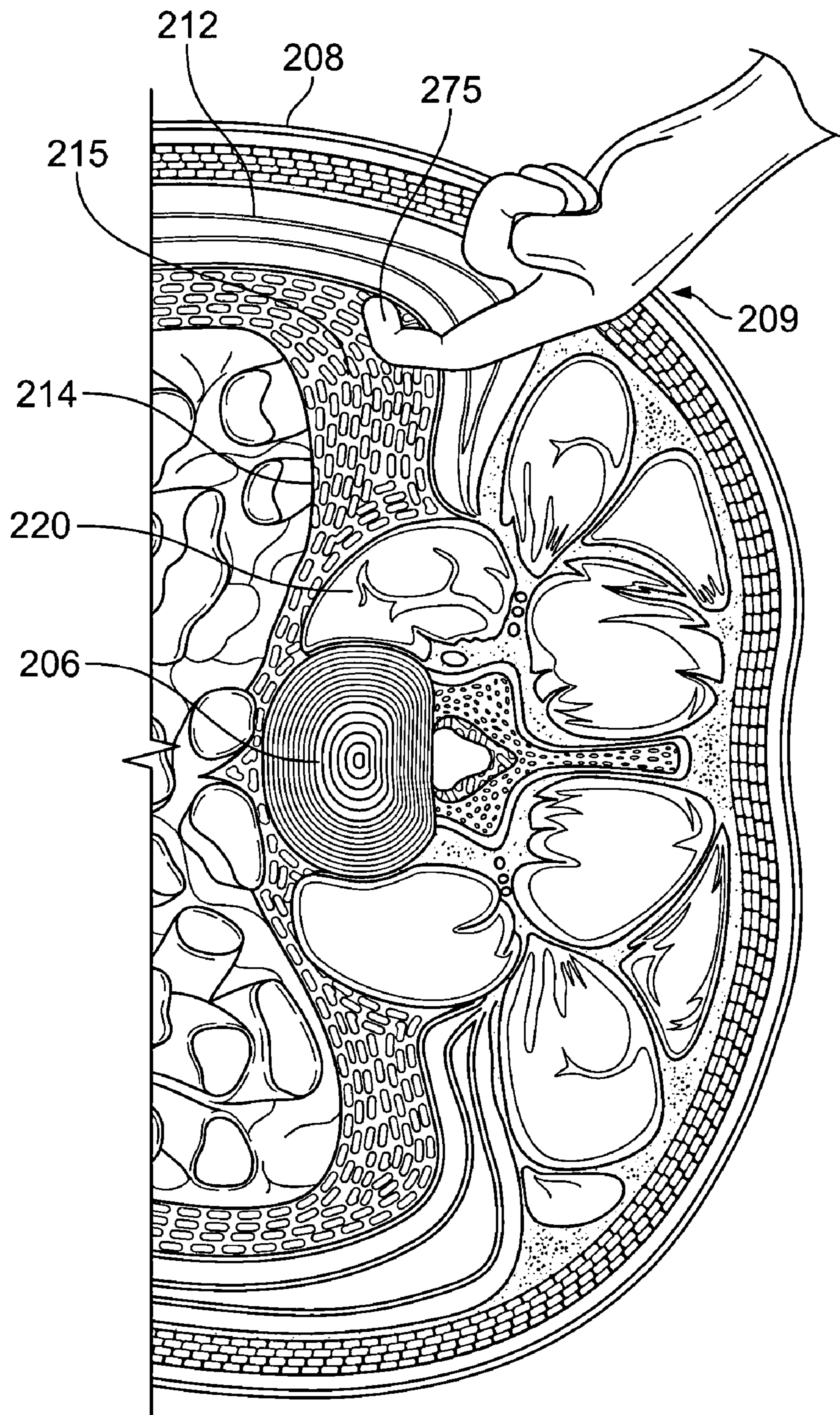


FIG. 32

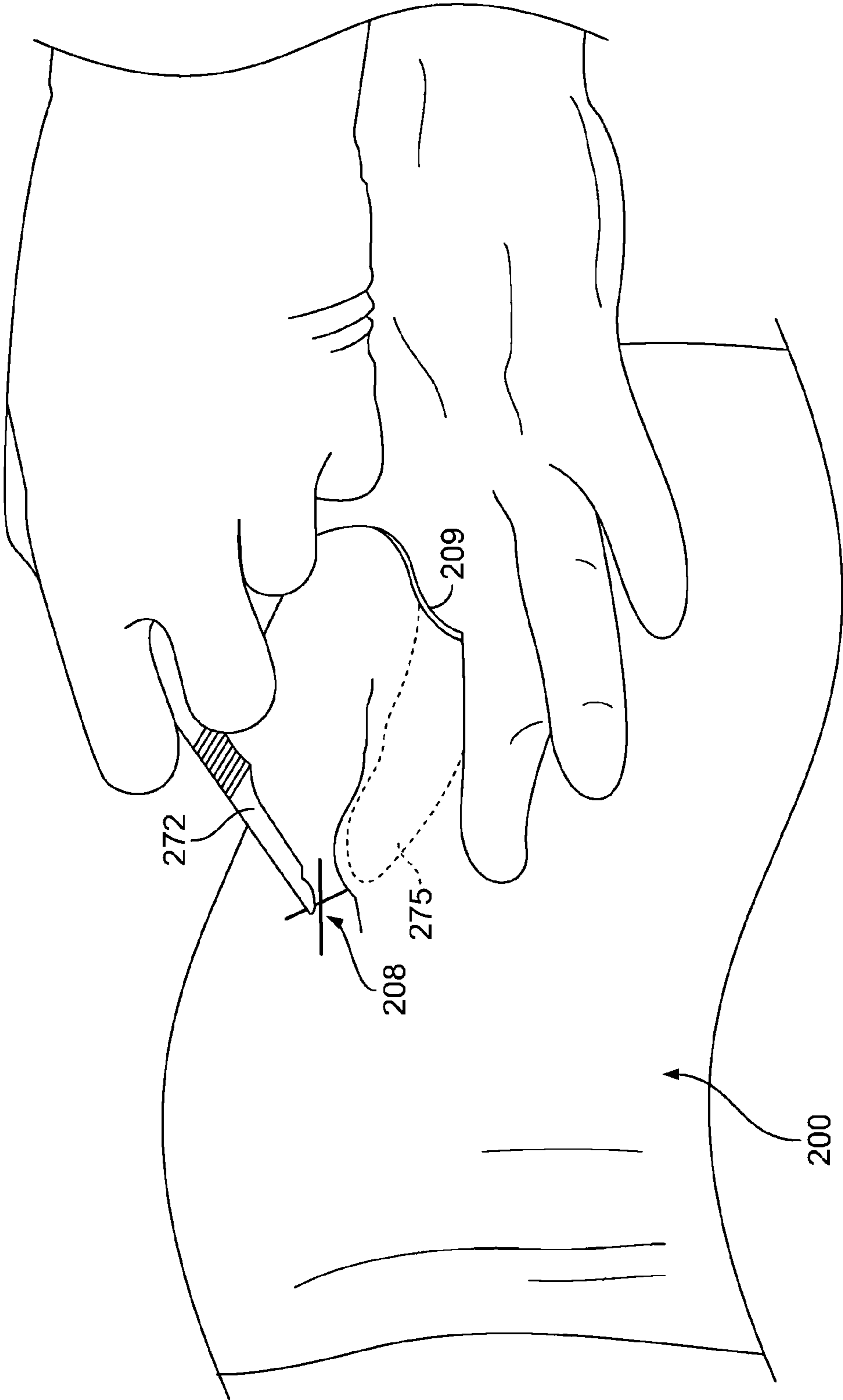


FIG. 33

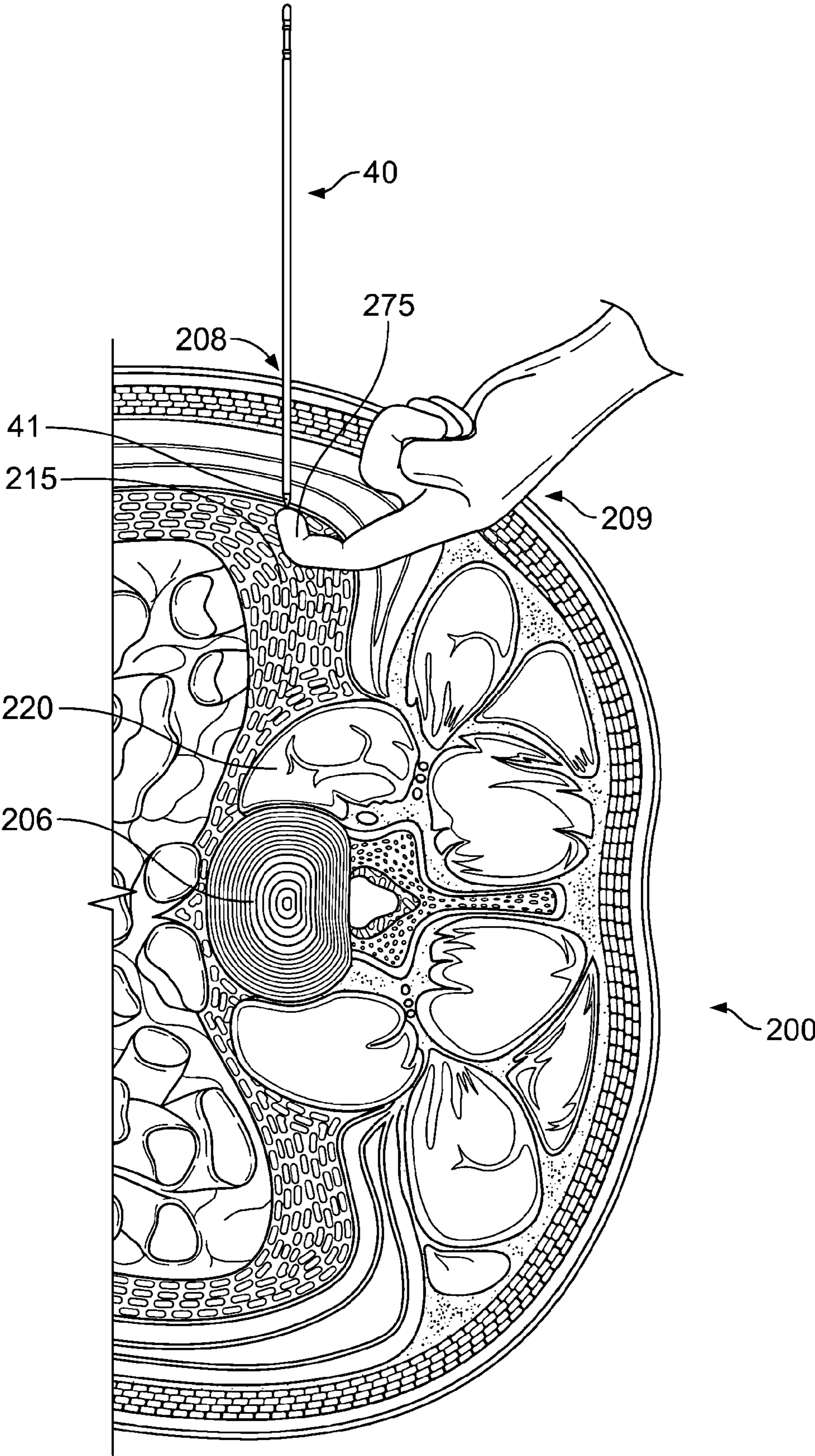


FIG. 34

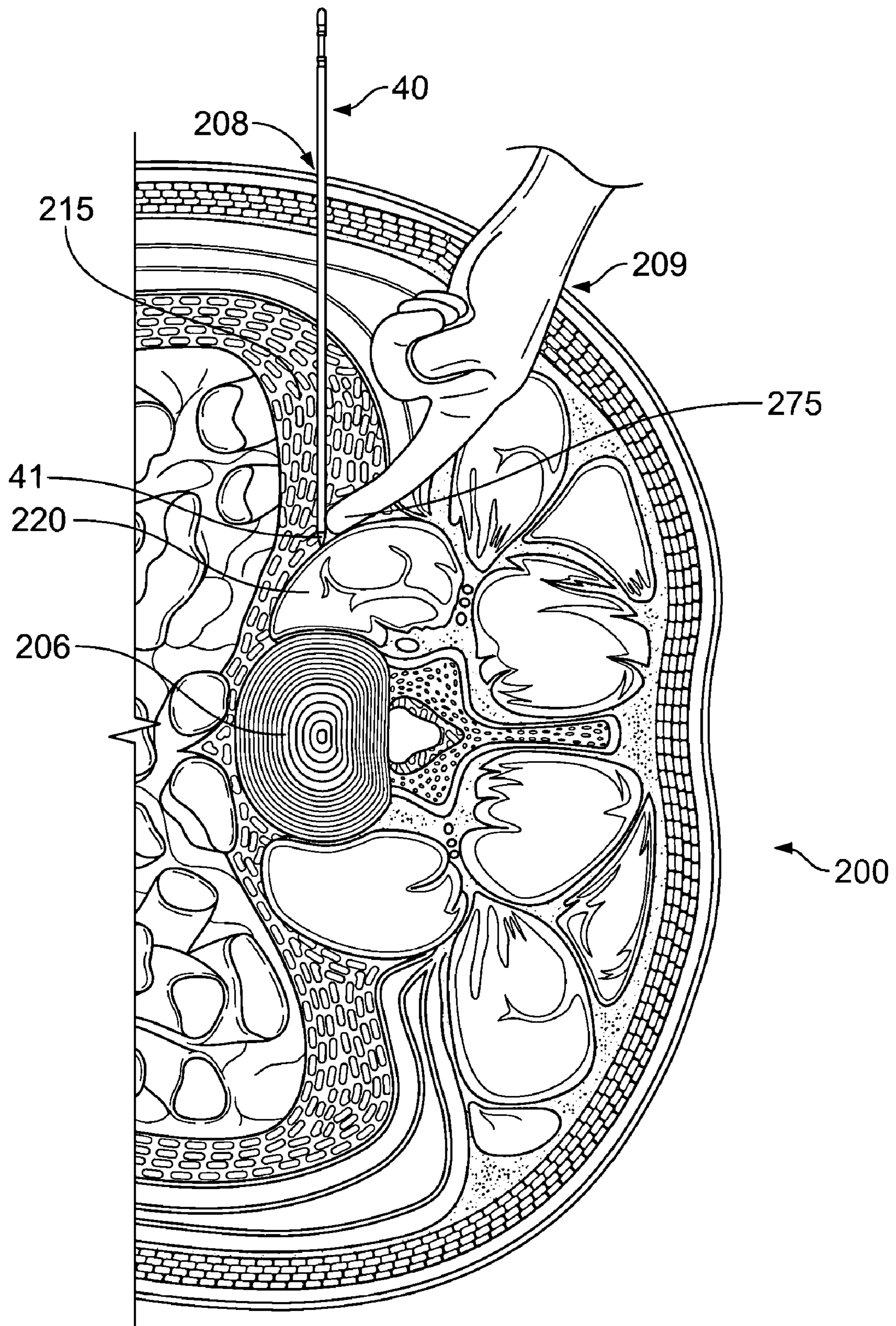


FIG. 35



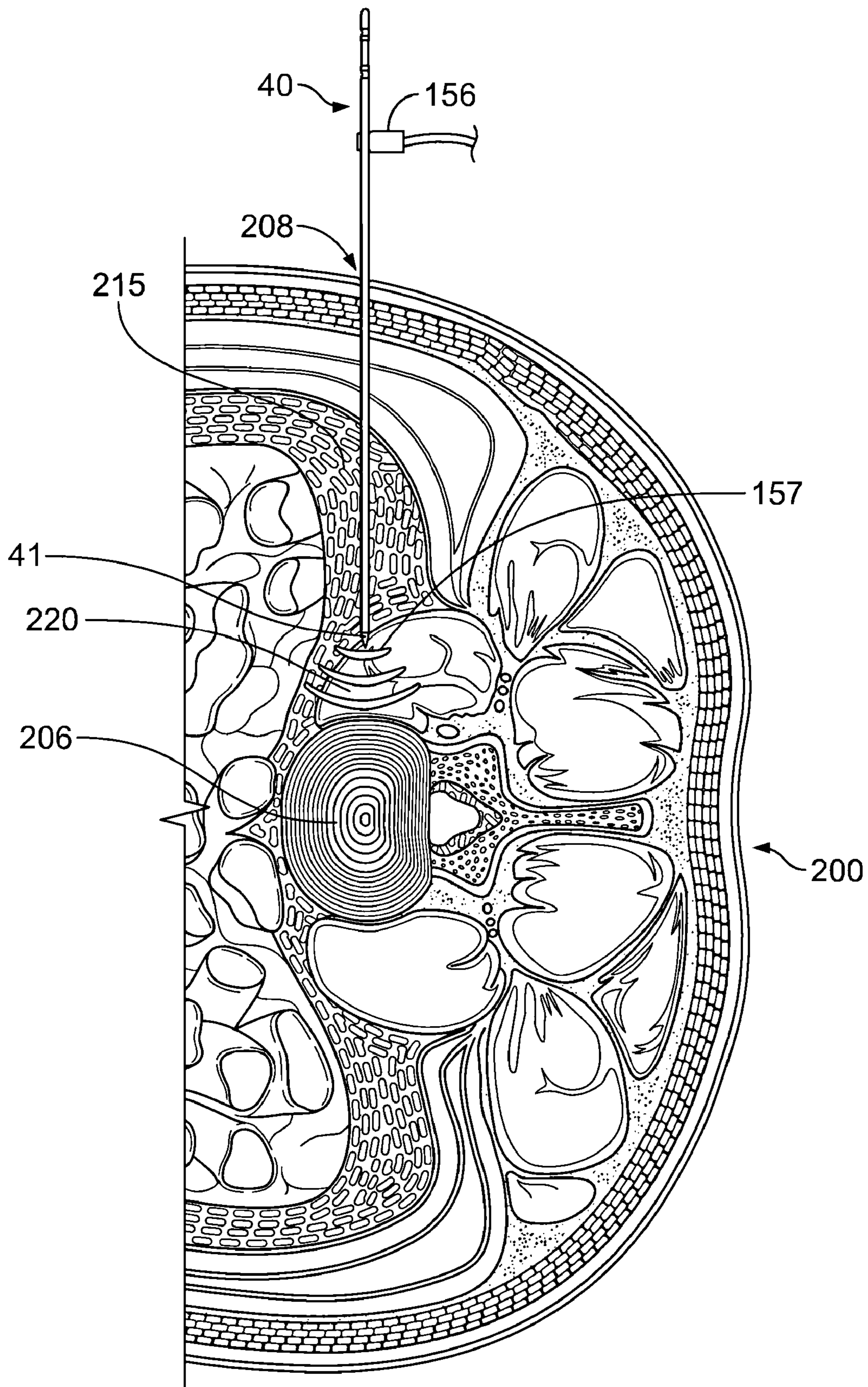


FIG. 36

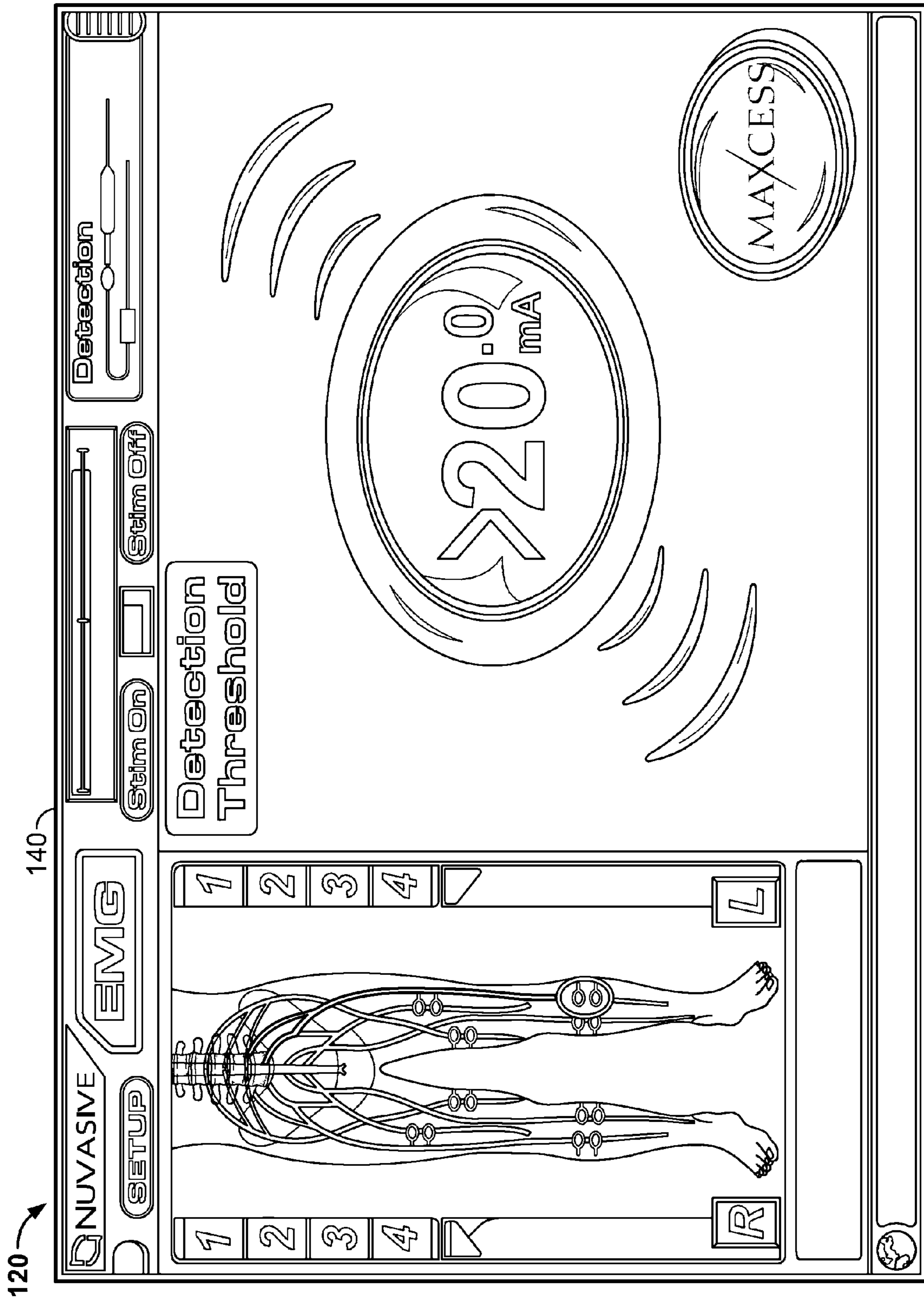


FIG. 37

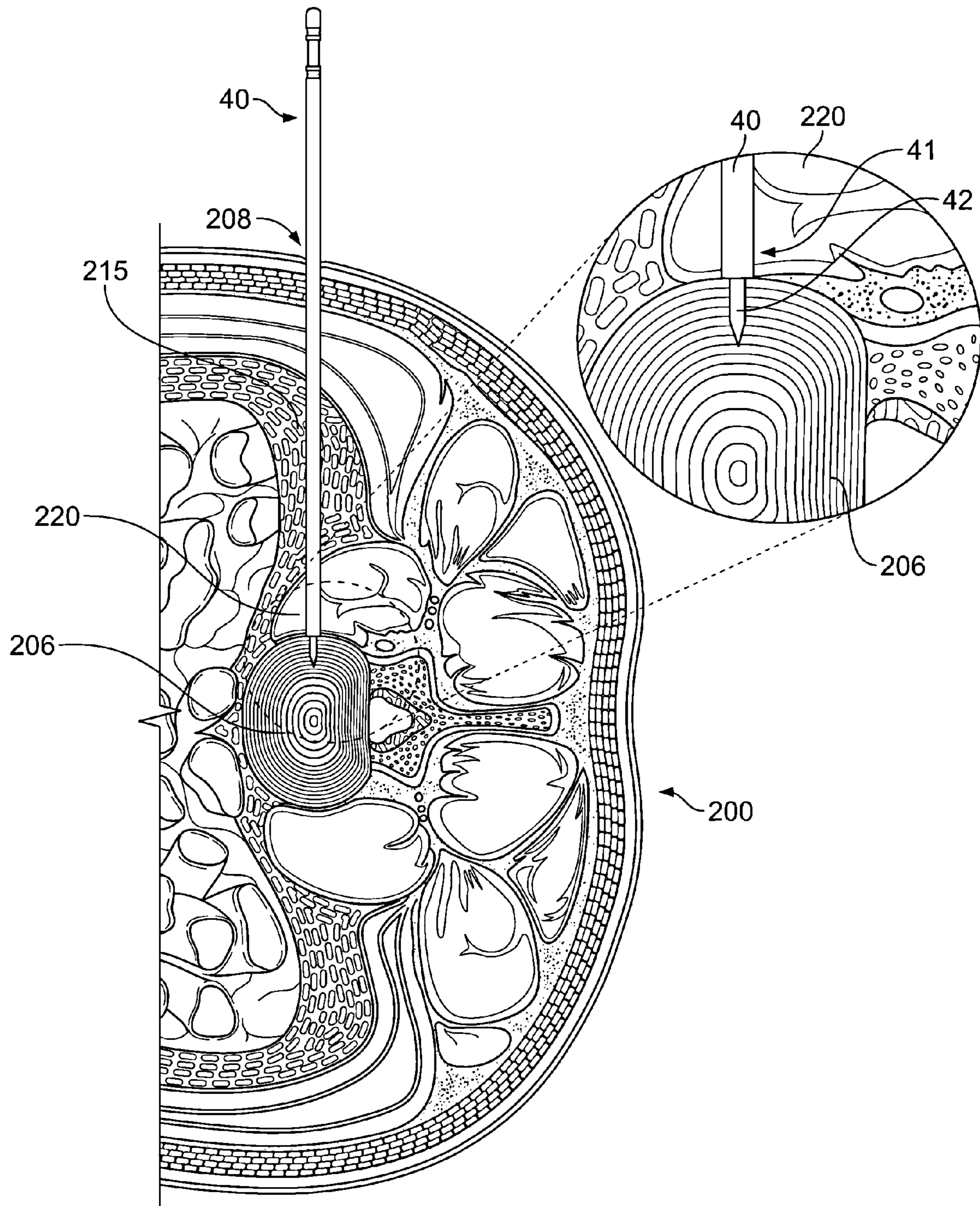


FIG. 38

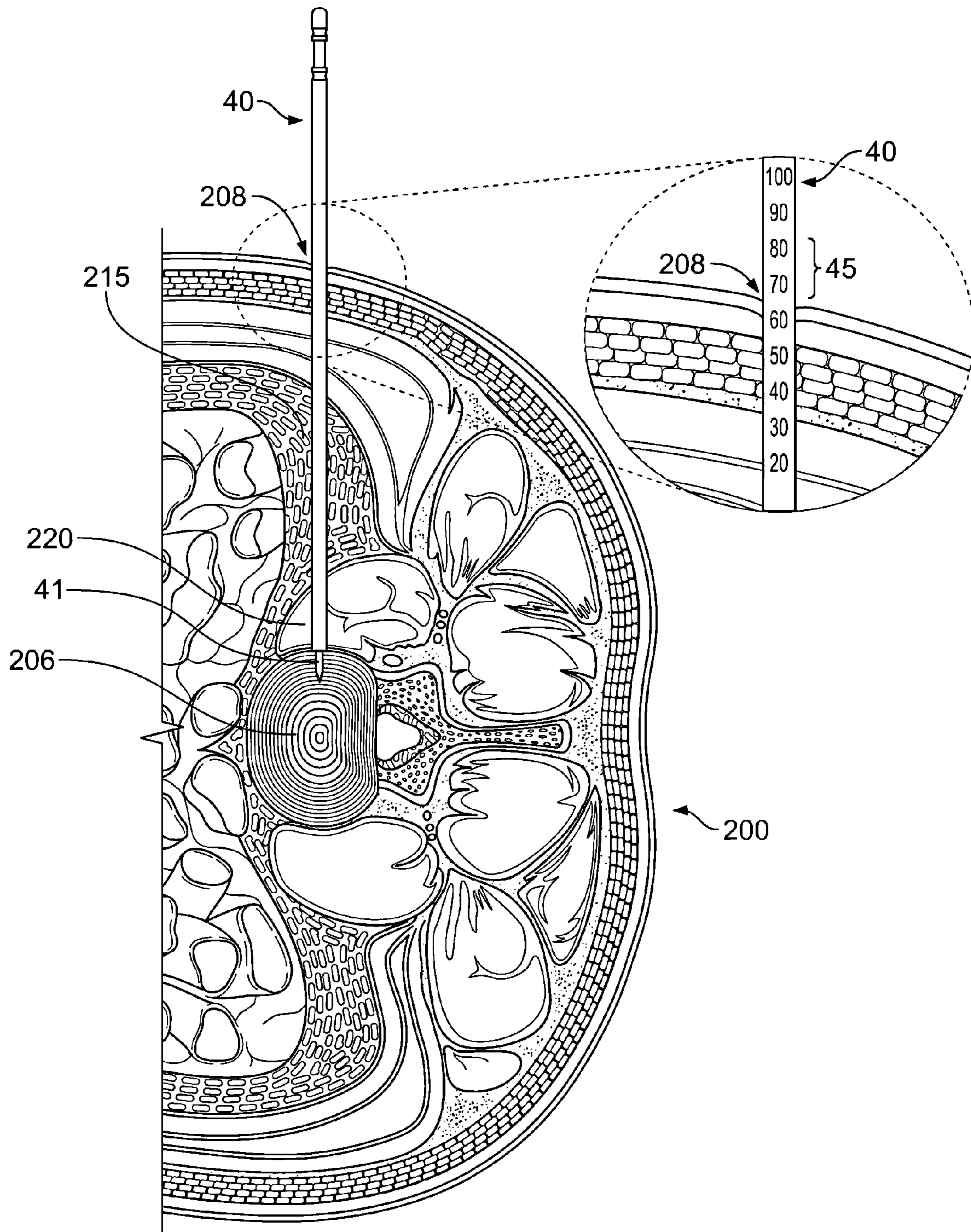


FIG. 39



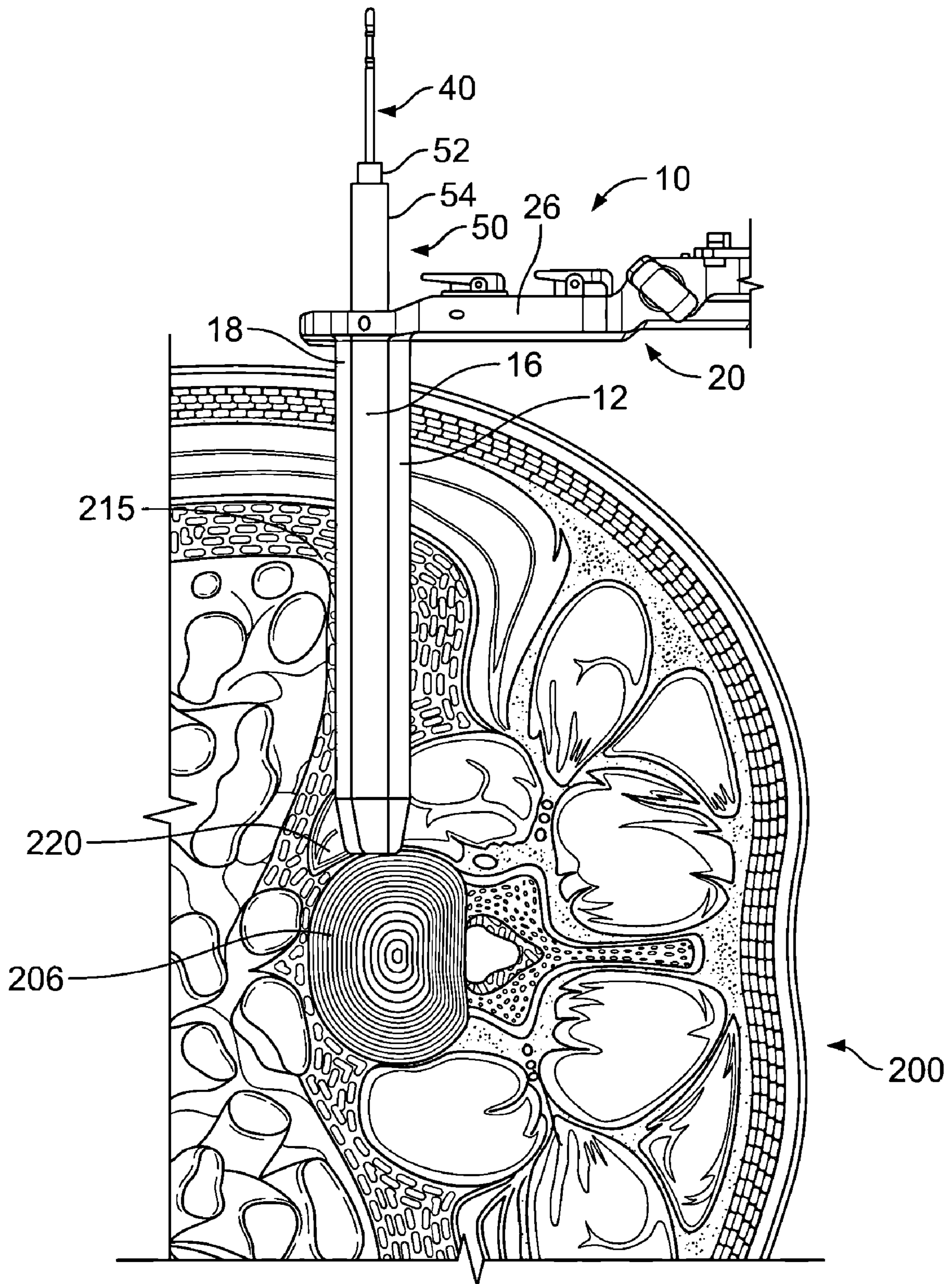


FIG. 41

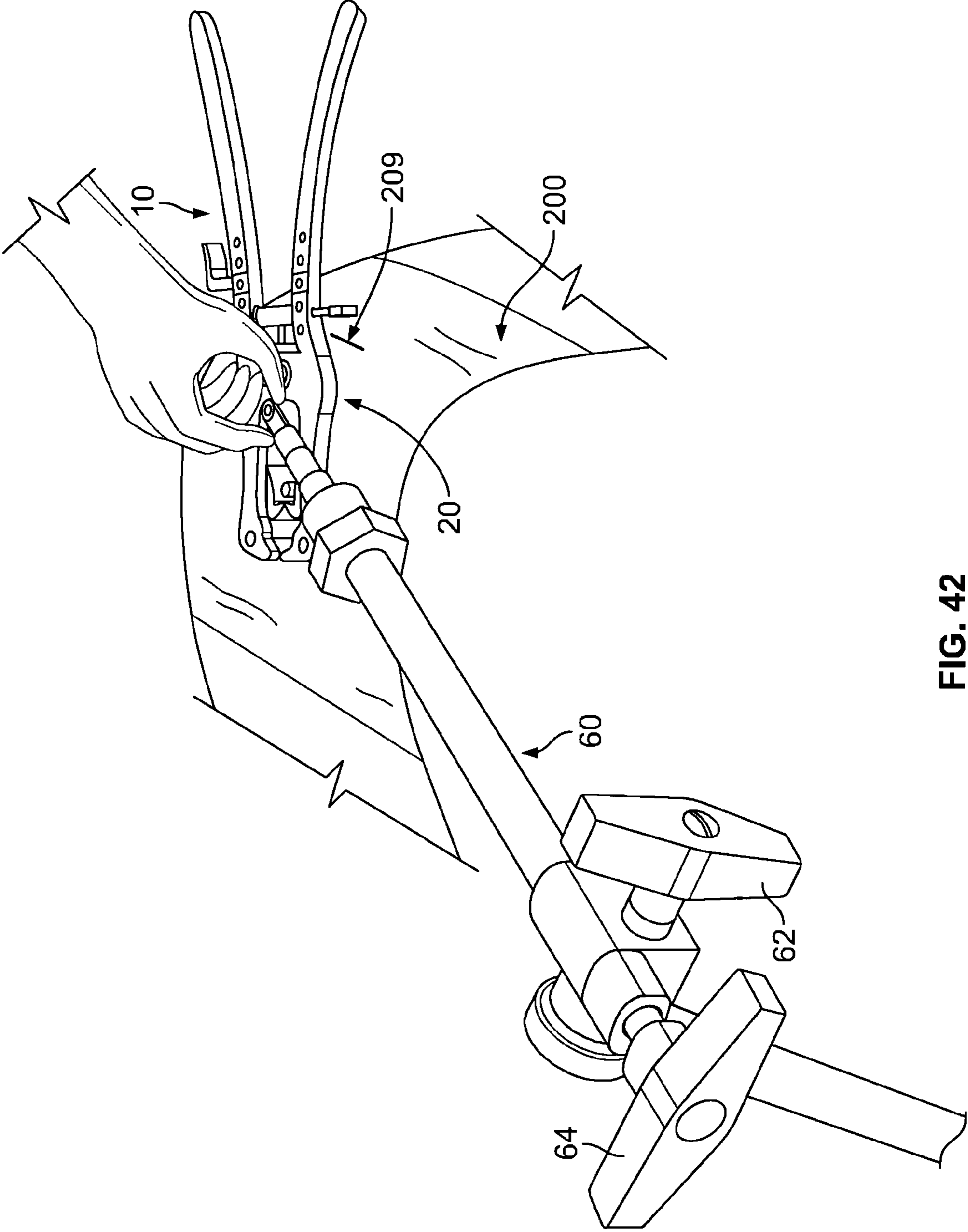


FIG. 42

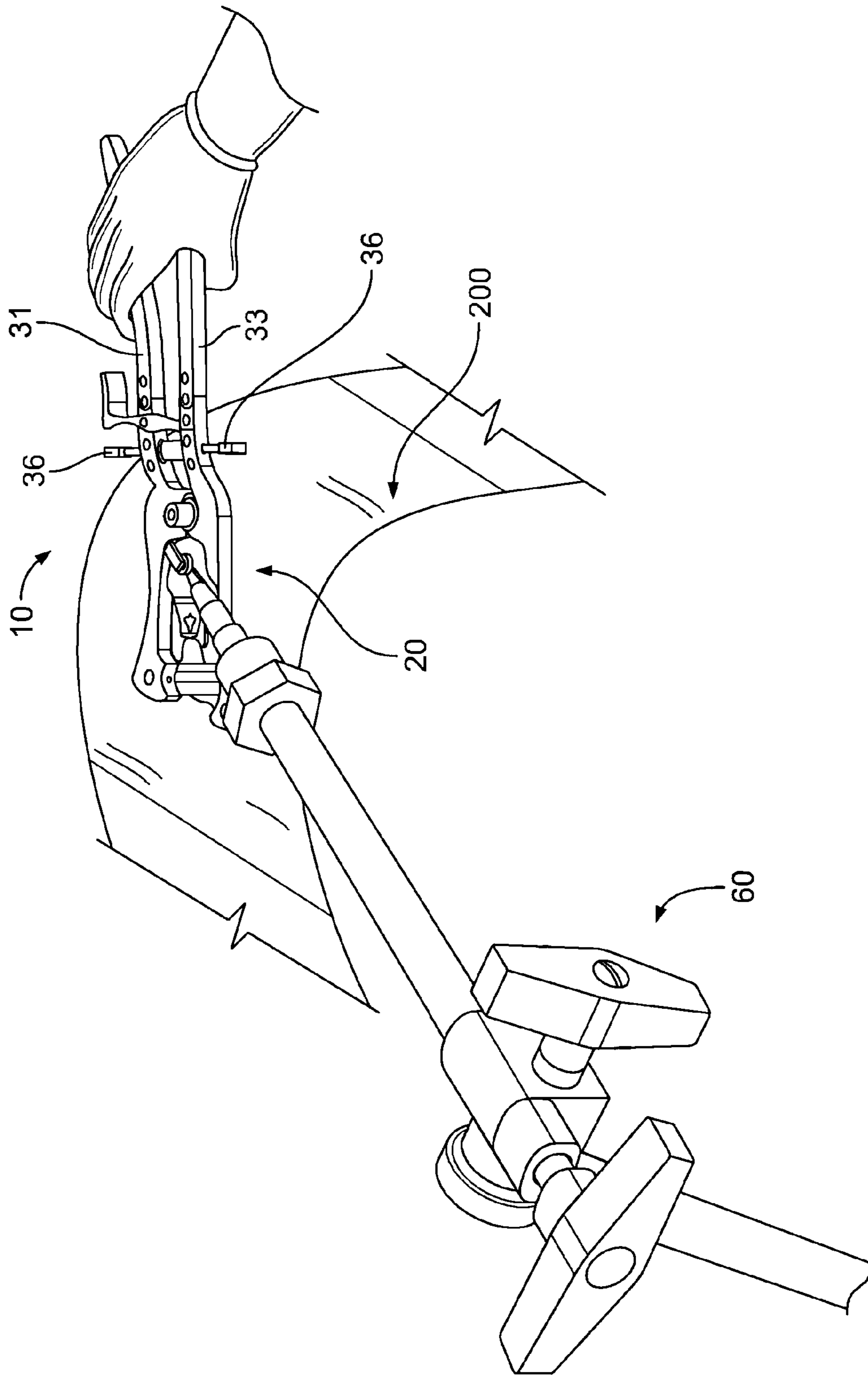


FIG. 43



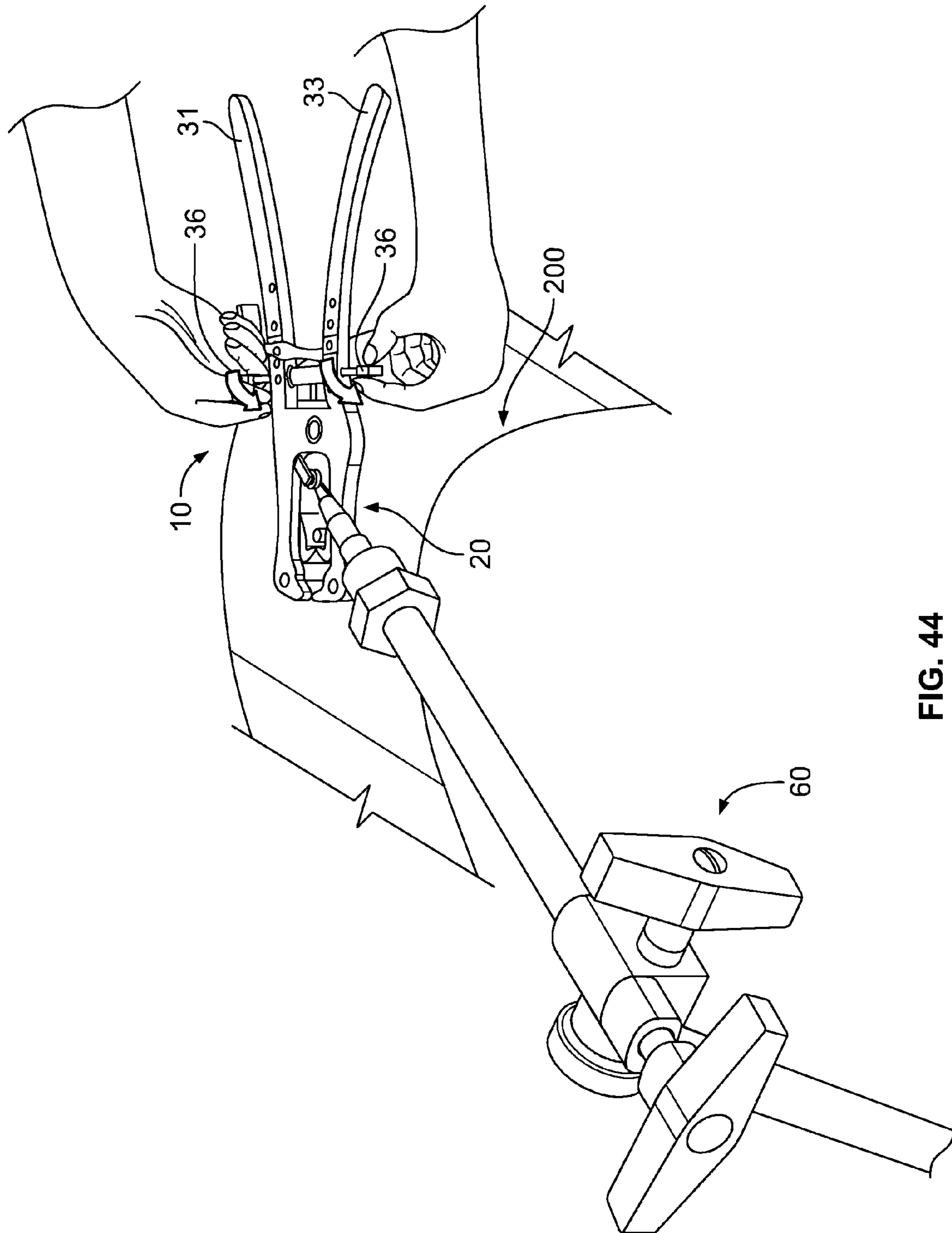


FIG. 44

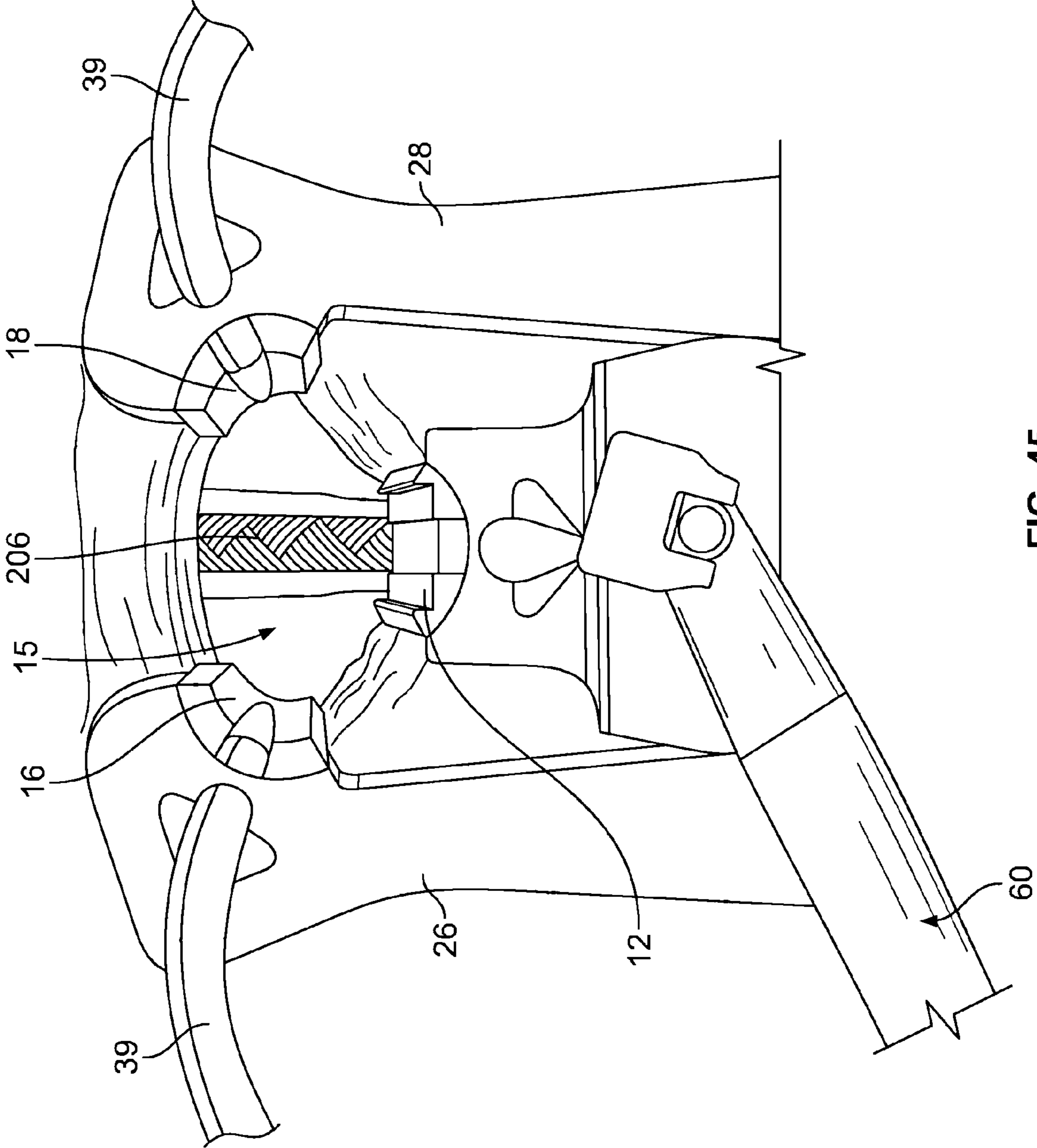


FIG. 45

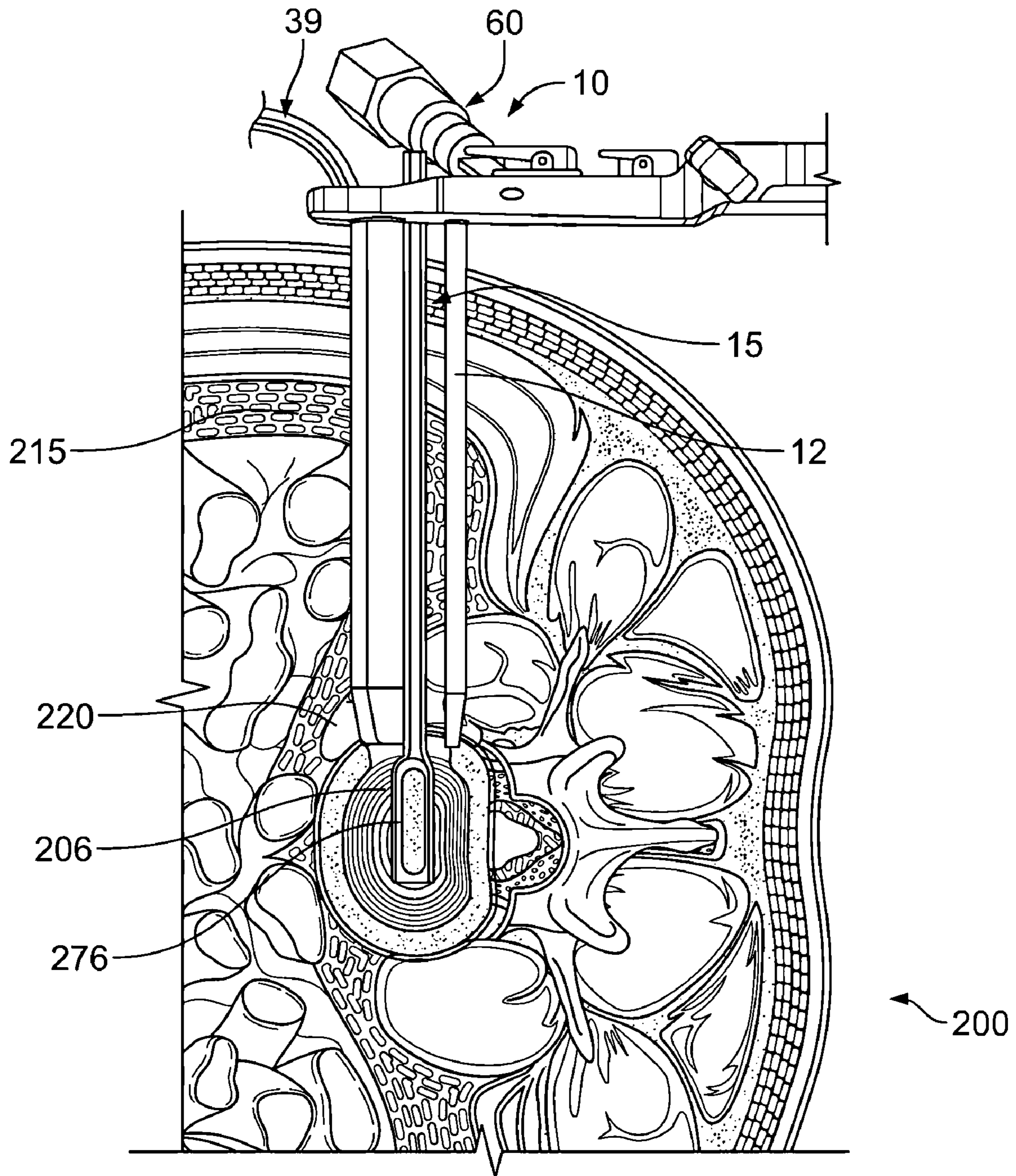


FIG. 46

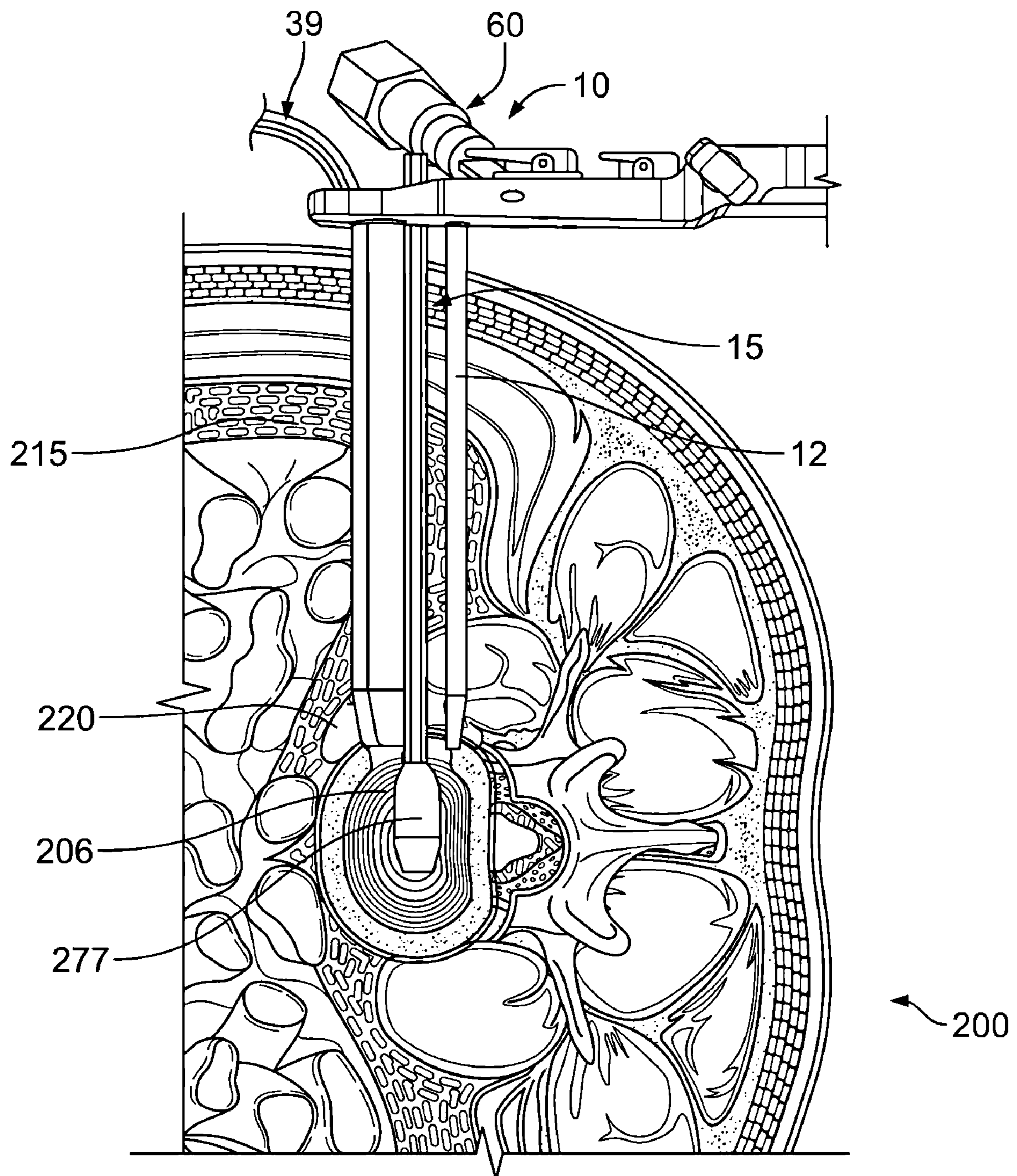


FIG. 47

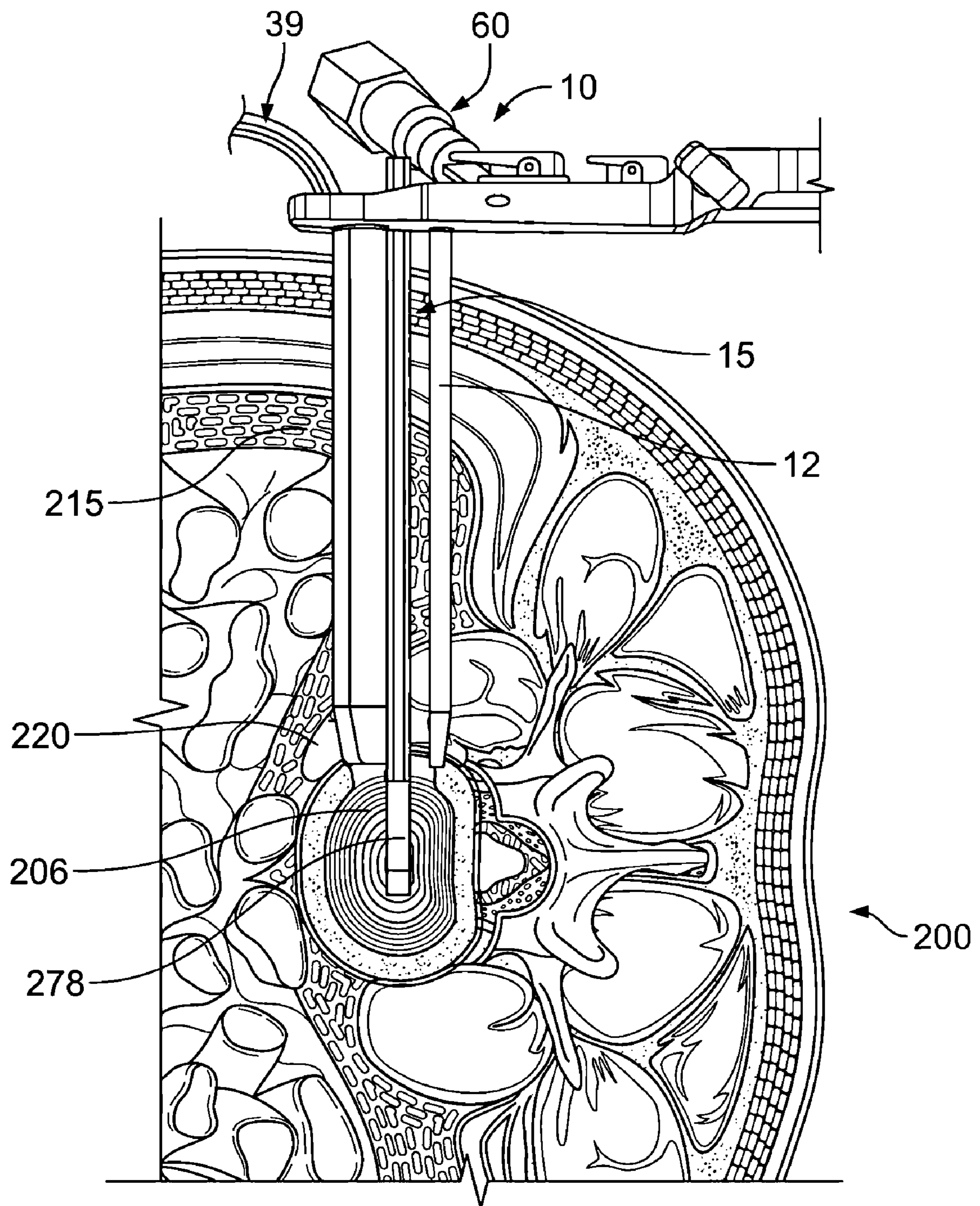


FIG. 48

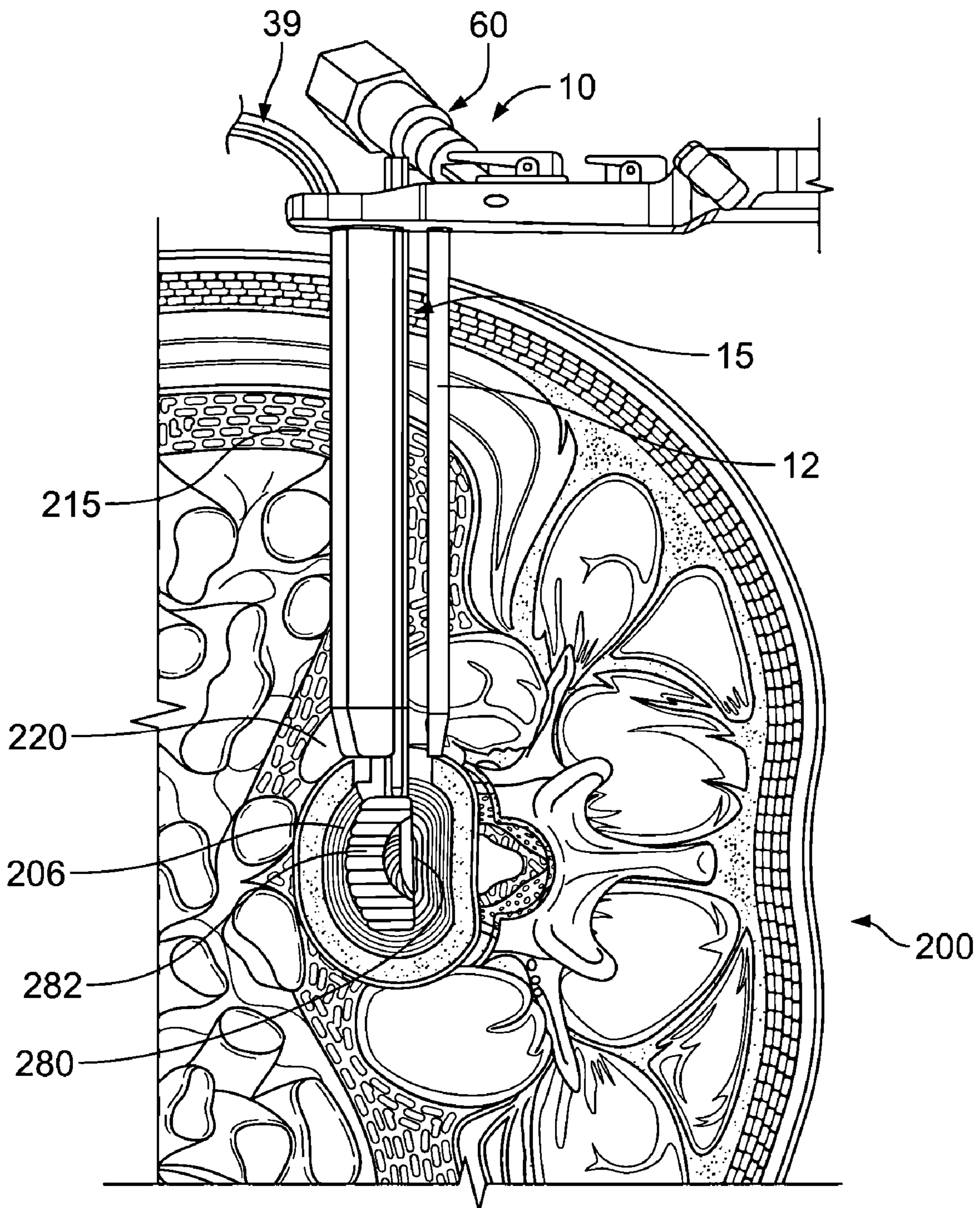
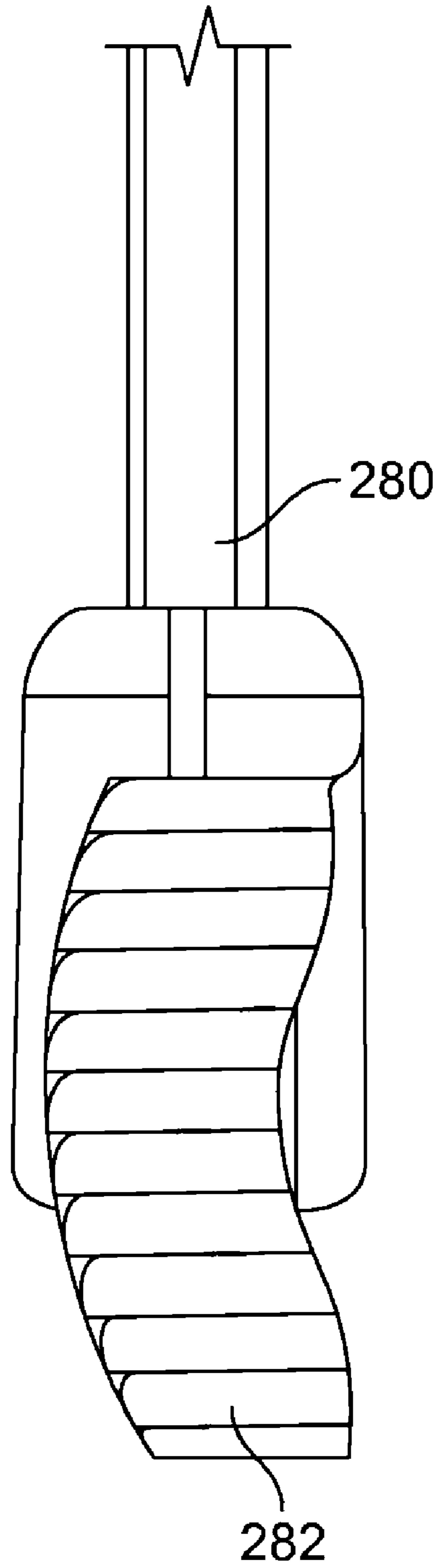


FIG. 49



**FIG. 50**

## SURGICAL ACCESS SYSTEM AND RELATED METHODS

### CROSS REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of priority from commonly owned and co-pending U.S. Provisional Patent Application Ser. No. 60/512,594 (filed on Oct. 17, 2003 by Curran et al.) entitled "System and Methods for Performing Lateral Lumbar Surgery," the entire contents of which is hereby expressly incorporated by reference into this disclosure as if set forth fully herein. The present application also incorporates by reference the following co-pending and co-assigned patent applications in their entireties: PCT App. Ser. No. PCT/US02/22247, entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery," filed on Jul. 11, 2002; PCT App. Ser. No. PCT/US02/30617, entitled "System and Methods for Performing Surgical Procedures and Assessments," filed on Sep. 25, 2002; PCT App. Ser. No. PCT/US02/35047, entitled "System and Methods for Performing Percutaneous Pedicle Integrity Assessments," filed on Oct. 30, 2002; and PCT App. Ser. No. PCT/US03/02056, entitled "System and Methods for Determining Nerve Direction to a Surgical Instrument," filed Jan. 15, 2003 (collectively "NeuroVision PCT Applications").

### BACKGROUND OF THE INVENTION

#### I. Field of the Invention

The present invention relates generally to systems and methods for performing surgical procedures and, more particularly, for accessing a surgical target site in order to perform surgical procedures.

#### II. Discussion of the Prior Art

A noteworthy trend in the medical community is the move away from performing surgery via traditional "open" techniques in favor of minimally invasive or minimal access techniques. Open surgical techniques are generally undesirable in that they typically require large incisions and high amounts of tissue displacement to gain access to the surgical target site, which produces concomitantly high amounts of pain, lengthened hospitalization (increasing health care costs), and high morbidity in the patient population. Less-invasive surgical techniques (including so-called "minimal access" and "minimally invasive" techniques) are gaining favor due to the fact that they involve accessing the surgical target site via incisions of substantially smaller size with greatly reduced tissue displacement requirements. This, in turn, reduces the pain, morbidity and cost associated with such procedures. The access systems developed to date, however, fail in various respects to meet all the needs of the surgeon population.

One drawback associated with prior art surgical access systems relates to the ease with which the operative corridor can be created, as well as maintained over time, depending upon the particular surgical target site. For example, when accessing surgical target sites located beneath or behind musculature or other relatively strong tissue (such as, by way of example only, the psoas muscle adjacent to the spine), it has been found that advancing an operative corridor-establishing instrument directly through such tissues can be challenging and/or lead to unwanted or undesirable effects (such as stressing or tearing the tissues). While certain efforts have been undertaken to reduce the trauma to tissue while creating an operative corridor, such as (by way of example only) the sequential dilation system of U.S. Pat. No. 5,792,044 to Foley et al., these attempts are nonetheless limited in their applica-

bility based on the relatively narrow operative corridor. More specifically, based on the generally cylindrical nature of the so-called "working cannula," the degree to which instruments can be manipulated and/or angled within the cannula can be generally limited or restrictive, particularly if the surgical target site is a relatively deep within the patient.

Efforts have been undertaken to overcome this drawback, such as shown in U.S. Pat. No. 6,524,320 to DiPoto, wherein an expandable portion is provided at the distal end of a cannula for creating a region of increased cross-sectional area adjacent to the surgical target site. While this system may provide for improved instrument manipulation relative to sequential dilation access systems (at least at deep sites within the patient), it is nonetheless flawed in that the deployment of the expandable portion may inadvertently compress or impinge upon sensitive tissues adjacent to the surgical target site. For example, in anatomical regions having neural and/or vasculature structures, such a blind expansion may cause the expandable portion to impinge upon these sensitive tissues and cause neural and/or vasculature compromise, damage and/or pain for the patient.

This highlights yet another drawback with the prior art surgical access systems, namely, the challenges in establishing an operative corridor through or near tissue having major neural structures which, if contacted or impinged, may result in neural impairment for the patient. Due to the threat of contacting such neural structures, efforts thus far have largely restricted to establishing operative corridors through tissue having little or substantially reduced neural structures, which effectively limits the number of ways a given surgical target site can be accessed. This can be seen, by way of example only, in the spinal arts, where the exiting nerve roots and neural plexus structures in the psoas muscle have rendered a lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine virtually impossible. Instead, spine surgeons are largely restricted to accessing the spine from the posterior (to perform, among other procedures, posterior lumbar interbody fusion (PLIF)) or from the anterior (to perform, among other procedures, anterior lumbar interbody fusion (ALIF)).

Posterior-access procedures involve traversing a shorter distance within the patient to establish the operative corridor, albeit at the price of oftentimes having to reduce or cut away part of the posterior bony structures (i.e. lamina, facets, spinous process) in order to reach the target site (which typically comprises the disc space). Anterior-access procedures are relatively simple for surgeons in that they do not involve reducing or cutting away bony structures to reach the surgical target site. However, they are nonetheless disadvantageous in that they require traversing through a much greater distance within the patient to establish the operative corridor, oftentimes requiring an additional surgeon to assist with moving the various internal organs out of the way to create the operative corridor.

The present invention is directed at eliminating, or at least minimizing the effects of, the above-identified drawbacks in the prior art.

### SUMMARY OF THE INVENTION

The present invention accomplishes this goal by providing a novel access system and related methods which involve detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impair-



ment for the patient. It is expressly noted that, although described herein largely in terms of use in spinal surgery, the access system of the present invention is suitable for use in any number of additional surgical procedures wherein tissue having significant neural structures must be passed through (or near) in order to establish an operative corridor.

According to one broad aspect of the present invention, the access system comprises a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures. The tissue distraction assembly (in conjunction with one or more elements of the tissue retraction assembly) is capable of, as an initial step, distracting a region of tissue between the skin of the patient and the surgical target site. The tissue retraction assembly is capable of, as a secondary step, being introduced into this distracted region to thereby define and establish the operative corridor. Once established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure. The electrode(s) are capable of, during both tissue distraction and retraction, detecting the existence of (and optionally the distance and/or direction to) neural structures such that the operative corridor may be established through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient. In this fashion, the access system of the present invention may be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

The tissue distraction assembly may include any number of components capable of performing the necessary distraction. By way of example only, the tissue distraction assembly may include a K-wire, an initial dilator of split construction, and one or more dilators of traditional (that is, non-split) construction for performing the necessary tissue distraction to receive the remainder of the tissue retractor assembly thereafter. One or more electrodes may be provided on one or more of the K-wire and dilator(s) to detect the presence of (and optionally the distance and/or direction to) neural structures during tissue distraction.

The tissue retraction assembly may include any number of components capable of performing the necessary retraction. By way of example only, the tissue retraction assembly may include one or more retractor blades extending from a handle assembly. The handle assembly may be manipulated to open the retractor assembly; that is, allowing the retractor blades to separate from one another (simultaneously or sequentially) to create an operative corridor to the surgical target site. In a preferred embodiment, this is accomplished by maintaining a posterior retractor blade in a fixed position relative to the surgical target site (so as to avoid having it impinge upon any exiting nerve roots near the posterior elements of the spine) while the additional retractor blades (i.e. cephalad-most and caudal-most blades) are moved or otherwise translated away from the posterior retractor blade (and each other) so as to create the operative corridor in a fashion that doesn't infringe upon the region of the exiting nerve roots.

The retractor blades may be optionally dimensioned to receive and direct a rigid shim element to augment the structural stability of the retractor blades and thereby ensure the operative corridor, once established, will not decrease or become more restricted, such as may result if distal ends of the retractor blades were permitted to "slide" or otherwise move in response to the force exerted by the displaced tissue.

In a preferred embodiment, only the posterior retractor blade is equipped with such a rigid shim element. In an optional aspect, this shim element may be advanced into the disc space after the posterior retractor blade is positioned, but before the retractor is opened into the fully retracted position. The rigid shim element is preferably oriented within the disc space such that it distracts the adjacent vertebral bodies, which serves to restore disc height. It also preferably advances a sufficient distance within the disc space (preferably past the midline), which serves the dual purpose of preventing post-operative scoliosis and forming a protective barrier (preventing the migration of tissue (such as nerve roots) into the operative field and the inadvertent advancement of instruments outside the operative field).

The retractor blades may optionally be equipped with a mechanism for transporting or emitting light at or near the surgical target site to aid the surgeon's ability to visualize the surgical target site, instruments and/or implants during the given surgical procedure. According to one embodiment, this mechanism may comprise, but need not be limited to, coupling one or more light sources to the retractor blades such that the terminal ends are capable of emitting light at or near the surgical target site. According to another embodiment, this mechanism may comprise, but need not be limited to, constructing the retractor blades of suitable material (such as clear polycarbonate) and configuration such that light may be transmitted generally distally through the walls of the retractor blade light to shine light at or near the surgical target site. This may be performed by providing the retractor blades having light-transmission characteristics (such as with clear polycarbonate construction) and transmitting the light almost entirely within the walls of the retractor blade (such as by frosting or otherwise rendering opaque portions of the exterior and/or interior) until it exits a portion along the interior (or medially-facing) surface of the retractor blade to shine at or near the surgical target site. The exit portion may be optimally configured such that the light is directed towards the approximate center of the surgical target site and may be provided along the entire inner periphery of the retractor blade or one or more portions therealong.

According to another aspect of the invention, a minimally invasive lateral lumbar surgery may be performed using various embodiments of the surgical access system. The surgical method may be accomplished by guiding at least a portion of the tissue distraction assembly to the surgical target site using a lateral, retroperitoneal approach. According to some embodiments, the access system is used to access the lumbar spine via a direct lateral, retroperitoneal approach. In such embodiments, blunt finger dissection may be used to safely enter the retroperitoneal space posteriorly and sweep the peritoneal cavity anteriorly. A distal end of the K-wire, and possibly other components of the tissue distraction assembly, are then escorted through the retroperitoneal space to the psoas muscle utilizing finger dissection. In some instances, the initial dilator is guided through the retroperitoneal space by a finger in contact with the distal end, so the potential of peritoneal disruption may be reduced.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. 1 is a perspective view of a tissue retraction assembly (in use) forming part of a surgical access system according to the present invention;

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FIGS. 2-3 are perspective views illustrating the front and back of a shim element for use with a posterior retractor blade of the retractor according to the retractor of the present invention;

FIGS. 4-5 are perspective views illustrating the front and back of a narrow retractor extender for use with one of a cephalad and caudal retractor blade according to the retractor of the present invention;

FIGS. 6-7 are perspective views illustrating the front and back of a wide retractor extender for use with one of a cephalad and caudal retractor blade according to the retractor of the present invention;

FIG. 8 is a perspective, partially exploded view of the retractor assembly of the present invention, without the retractor blades;

FIG. 9 is a perspective view illustrating the components and use of an initial distraction assembly (i.e. K-wire, an initial dilating cannula with handle, and a split-dilator housed within the initial dilating cannula) forming part of the surgical access system according to the present invention, for use in distracting to a surgical target site (i.e. annulus);

FIG. 10 is a perspective view illustrating the K-wire and split-dilator of the initial distraction assembly with the initial dilating cannula and handle removed;

FIG. 11 is a posterior view of the vertebral target site illustrating the split-dilator of the present invention in use distracting in a generally cephalad-caudal fashion according to one aspect of the present invention;

FIG. 12 is a side view illustrating the use of a secondary distraction assembly (comprising a plurality of dilating cannulae over the K-wire) to further distract tissue between the skin of the patient and the surgical target site according to the present invention;

FIG. 13 is a side view of a retractor assembly according to the present invention, comprising a handle assembly having three (3) retractor blades extending there from (posterior, cephalad-most, and caudal-most) disposed over the secondary distraction assembly of FIG. 12 (shown in a first, closed position);

FIG. 14 is a side view of a retractor assembly according to the present invention, comprising a handle assembly having three (3) retractor blades extending there from (posterior, cephalad-most, and caudal-most) with the secondary distraction assembly of FIG. 12 removed and shim element introduced;

FIGS. 15-16 are perspective and top views, respectively, of the retractor assembly in a second, opened (i.e. retracted) position to thereby create an operative corridor to a surgical target site according to the present invention;

FIGS. 17-18 are perspective and side views, respectively, of the retractor assembly in the second, opened (i.e. retracted) position (with the secondary distraction assembly removed) and with the retractor extenders of FIGS. 4-5 and 6-7 coupled to the retractor according to the present invention.

FIG. 19 is a perspective view of an exemplary nerve monitoring system capable of performing nerve monitoring before, during and after the creating of an operative corridor to a surgical target site using the surgical access system in accordance with the present invention;

FIG. 20 is a block diagram of the nerve monitoring system shown in FIG. 19; and

FIGS. 21-22 are screen displays illustrating exemplary features and information communicated to a user during the use of the nerve monitoring system of FIG. 19.

FIGS. 23-50 illustrate a method for accessing a surgical target site in the spine using a substantially lateral, retroperitoneal approach.

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## DESCRIPTION OF THE PREFERRED EMBODIMENT

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. It is furthermore to be readily understood that, although discussed below primarily within the context of spinal surgery, the surgical access system of the present invention may be employed in any number of anatomical settings to provide access to any number of different surgical target sites throughout the body. The surgical access system disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

The present invention involves accessing a surgical target site in a fashion less invasive than traditional "open" surgeries and doing so in a manner that provides access in spite of the neural structures required to be passed through (or near) in order to establish an operative corridor to the surgical target site. Generally speaking, the surgical access system of the present invention accomplishes this by providing a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures. In some embodiments, the surgical access system may be used access a surgical target site on the spine via a substantially lateral, retroperitoneal approach (as shown, for example, in FIGS. 23-50).

These electrodes are preferably provided for use with a nerve surveillance system such as, by way of example, the type shown and described in the co-pending and commonly assigned NeuroVision PCT Applications referenced above, the entire contents of which are expressly incorporated by reference as if set forth herein in their entirety. Generally speaking, this nerve surveillance system is capable of detecting the existence of (and optionally the distance and/or direction to) neural structures during the distraction and retraction of tissue by detecting the presence of nerves by applying a stimulation signal to such instruments and monitoring the evoked EMG signals from the myotomes associated with the nerves being passed by the distraction and retraction systems of the present invention. In so doing, the system as a whole (including the surgical access system of the present invention) may be used to form an operative corridor through (or near) any of a variety of tissues having such neural structures, particularly those which, if contacted or impinged, may otherwise result in neural impairment for the patient. In this fashion, the access system of the present invention may be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

The tissue distraction assembly of the present invention (comprising a K-wire, an initial dilator, and a split-dilator disposed within the initial dilator) is employed to distract the tissues extending between the skin of the patient and a given surgical target site (preferably along the posterior region of the target intervertebral disc). A secondary distraction assem-

bly (i.e. a plurality of sequentially dilating cannulae) may optionally be employed after the initial distraction assembly to further distract the tissue. Once distracted, the resulting void or distracted region within the patient is of sufficient size to accommodate a tissue retraction assembly of the present invention. More specifically, the tissue retraction assembly (comprising a plurality of retractor blades extending from a handle assembly) may be advanced relative to the secondary distraction assembly such that the retractor blades, in a first, closed position, are advanced over the exterior of the secondary distraction assembly. At that point, the handle assembly may be operated to move the retractor blades into a second, open or "retracted" position to create an operative corridor to the surgical target site.

According to one aspect of the invention, following (or before) this retraction, a posterior shim element (which is preferably slideably engaged with the posterior retractor blade) may be advanced such that a distal shim extension is positioned within the posterior region of the disc space. If done before retraction, this helps ensure that the posterior retractor blade will not move posteriorly during the retraction process, even though the other retractor blades (i.e. cephalad-most and caudal-most) are able to move and thereby create an operative corridor. Fixing the posterior retractor blade in this fashion serves several important functions. First, the distal end of the shim element serves to distract the adjacent vertebral bodies, thereby restoring disc height. It also rigidly couples the posterior retractor blade in fixed relation relative to the vertebral bodies. The posterior shim element also helps ensure that surgical instruments employed within the operative corridor are incapable of being advanced outside the operative corridor, preventing inadvertent contact with the exiting nerve roots during the surgery. Once in the appropriate retracted state, the cephalad-most and caudal-most retractor blades may be locked in position and, thereafter, retractor extenders advanced therealong to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc. . . .) into or out of the operative corridor. Once the operative corridor is established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure.

FIG. 1 illustrates a tissue retraction assembly 10 forming part of a surgical access system according to the present invention. The retraction assembly 10 includes a plurality of retractor blades extending from a handle assembly 20. By way of example only, the handle assembly 20 is provided with a first retractor blade 12, a second retractor blade 16, and a third retractor blade 18. The retractor assembly 10 is shown in a fully retracted or "open" configuration, with the retractor blades 12, 16, 18 positioned a distance from one another so as to form an operative corridor 15 there between and extending to a surgical target site (e.g. an annulus of an intervertebral disc). Although shown and described below with regard to the three-bladed configuration, it is to be readily appreciated that the number of retractor blades may be increased or decreased without departing from the scope of the present invention. Moreover, although described and shown herein, for example in FIGS. 1, 9-18, and 23-50, with reference to a generally lateral approach to a spinal surgical target site (with the first blade 12 being the "posterior" blade, the second blade 16 being the "cephalad-most" blade, and the third blade 18 being the "caudal-most" blade), it will be appreciated that the retractor assembly 10 of the present invention may find use in any number of different surgical approaches, including generally posterior, generally postero-lateral, generally anterior and generally antero-lateral.

The retractor blades 12, 16, 18 may be equipped with various additional features or components. By way of example only, posterior retractor blade 12 may be equipped with a shim element 22 (shown more clearly in FIGS. 2-3). Shim element 22 serves to distract the adjacent vertebral bodies (thereby restoring disc height), helps secure the retractor assembly 10 relative to the surgical target site, and forms a protective barrier to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc. . . .) into or out of the operative corridor. Each of the remaining retractor blades (cephalad-most blade 16 and caudal-most blade 18) may be equipped with a retractor extender, such as the narrow retractor extender 24 shown in FIGS. 4-5 or the wide retractor extender 25 shown in FIGS. 6-7. The retractor extenders 24/25 extend from the cephalad-most and caudal-most retractor blades 16, 18 to form a protective barrier to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc. . . .) into or out of the operative corridor 15.

According to the present invention, any or all of the retractor blades 12, 16, 18, the shim element 22 and/or the retractor extenders 24/25 may be provided with one or more electrodes 39 (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications. Each of the shim element 22 and/or the retractor extenders 24/25 may also be equipped with a mechanism to selectively and releasably engage with the respective retractor blades 12, 16, 18. By way of example only, this may be accomplished by configuring the shim element 22 and/or the retractor extenders 24/25 with a tab element 27 capable of engaging with corresponding ratchet-like grooves (shown at 29 in FIG. 1) along the inner-facing surfaces of the retractor blades 12, 16, 18. Each of the shim element 22 and/or the retractor extenders 24/25 is provided with a pair of engagement elements 37 having, by way of example only, a generally dove-tailed cross-sectional shape. The engagement elements 37 are dimensioned to engage with receiving portions on the respective retractor blades 12, 16, 18. In a preferred embodiment, each of the shim element 22 and/or the retractor extenders 24/25 are provided with an elongate slot 43 for engagement with an insertion tool (not shown). Each tab member 27 is also equipped with an enlarged tooth element 49 which engages within corresponding grooves 29 provided along the inner surface of the retractor blades 12, 16, 18.

The handle assembly 20 may be coupled to any number of mechanisms for rigidly registering the handle assembly 20 in fixed relation to the operative site, such as through the use of an articulating arm mounted to the operating table. The handle assembly 20 includes first and second arm members 26, 28 hingedly coupled via coupling mechanism shown generally at 30. The cephalad-most retractor blade 16 is rigidly coupled (generally perpendicularly) to the end of the first arm member 26. The caudal-most retractor blade 18 is rigidly coupled (generally perpendicularly) to the end of the second arm member 28. The posterior retractor blade 12 is rigidly coupled (generally perpendicularly to) a translating member 17, which is coupled to the handle assembly 20 via a linkage assembly shown generally at 14. The linkage assembly 14 includes a roller member 34 having a pair of manual knob members 36 which, when rotated via manual actuation by a user, causes teeth 35 on the roller member 34 to engage within ratchet-like grooves 37 in the translating member 17. Thus, manual operation of the knobs 36 causes the translating member 17 to move relative to the first and second arm members 26, 28.

Through the use of handle extenders **31, 33** (FIG. **8**), the arms **26, 28** may be simultaneously opened such that the cephalad-most and caudal-most retractor blades **16, 18** move away from one another. In this fashion, the dimension and/or shape of the operative corridor **15** may be tailored depending upon the degree to which the translating member **17** is manipulated relative to the arms **26, 28**. That is, the operative corridor **15** may be tailored to provide any number of suitable cross-sectional shapes, including but not limited to a generally circular cross-section, a generally ellipsoidal cross-section, and/or an oval cross-section. Optional light emitting devices **39** may be coupled to one or more of the retractor blades **12, 16, 18** to direct light down the operative corridor **15**.

FIG. **9** illustrates an initial distraction assembly **40** forming part of the surgical access system according to the present invention. The initial distraction assembly **40** includes a K-wire **42**, an initial dilating cannula **44** with handle **46**, and a split-dilator **48** housed within the initial dilating cannula **44**. In use, the K-wire **42** and split-dilator **48** are disposed within the initial dilating cannula **44** and the entire assembly **40** advanced through the tissue towards the surgical target site (i.e. annulus). One exemplary method for advancing an initial dilator towards a spinal target site is described in more detail later in connection with FIGS. **23-50**. Again, this is preferably accomplished while employing the nerve detection and/or direction features described above. After the initial dilating assembly **40** is advanced such that the distal ends of the split-dilator **48** and initial dilator **44** are positioned within the disc space (FIG. **9**), the initial dilator **44** and handle **46** are removed (FIG. **10**) to thereby leave the split-dilator **48** and K-wire **42** in place. As shown in FIG. **11**, the split-dilator **48** is thereafter split such that the respective halves **48a, 48b** are separated from one another to distract tissue in a generally cephalad-caudal fashion relative to the target site. The split dilator **48** may thereafter be relaxed (allowing the dilator halves **48a, 48b** to come together) and rotated such that the dilator halves **48a, 48b** are disposed in the anterior-posterior plane. Once rotated in this manner, the dilator halves **48a, 48b** are again separated to distract tissue in a generally anterior-posterior fashion. Each dilator halve **48a, 48b** may be, according to the present invention, provided with one or more electrodes (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications.

Following this initial distraction, a secondary distraction may be optionally undertaken, such as via a sequential dilation system **50** as shown in FIG. **12**. According to the present invention, the sequential dilation system **50** may include the K-wire **42**, the initial dilator **44**, and one or more supplemental dilators **52, 54** for the purpose of further dilating the tissue down to the surgical target site. Once again, each component of the secondary distraction assembly **50** (namely, the K-wire **42**, the initial dilator **44**, and the supplemental dilators **52, 54**) may be, according to the present invention, provided with one or more electrodes (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications.

As shown in FIG. **13**, the retraction assembly **10** of the present invention is thereafter advanced along the exterior of the sequential dilation system **50**. This is accomplished by maintaining the retractor blades **12, 16, 18** in a first, closed position (with the retractor blades **12-16** in generally abutting relation to one another). Once advanced to the surgical target site, the sequential dilation assembly **50** may be removed and

the shim element **22** engaged with the posterior retractor blade **12** such that the distal end thereof extends into the disc space as shown in FIG. **14**. At this point, the handle assembly **20** may be operated to move the retractor blades **16, 18** into a second, open or "retracted" position as shown generally in FIGS. **15-16**. As one can see, the posterior retractor blade **12** is allowed to stay in the same general position during this process, such that the cephalad-most and caudal-most retractor blades **14, 16** move away from the posterior retractor blade **12**. At this point, the narrow and wide retractor extenders **24, 25** may be engaged with the caudal-most retractor blade **18** and cephalad-most retractor blade **16**, respectively, as shown in FIGS. **17-18**.

As mentioned above, any number of distraction components and/or retraction components (including but not limited to those described herein) may be equipped to detect the presence of (and optionally the distance and/or direction to) neural structures during the steps tissue distraction and/or retraction. This is accomplished by employing the following steps: (1) one or more stimulation electrodes are provided on the various distraction and/or retraction components; (2) a stimulation source (e.g. voltage or current) is coupled to the stimulation electrodes; (3) a stimulation signal is emitted from the stimulation electrodes as the various components are advanced towards or maintained at or near the surgical target site; and (4) the patient is monitored to determine if the stimulation signal causes muscles associated with nerves or neural structures within the tissue to innervate. If the nerves innervate, this may indicate that neural structures may be in close proximity to the distraction and/or retraction components.

Neural monitoring may be accomplished via any number of suitable fashions, including but not limited to observing visual twitches in muscle groups associated with the neural structures likely to found in the tissue, as well as any number of monitoring systems, including but not limited to any commercially available "traditional" electromyography (EMG) system (that is, typically operated by a neurophysiologist). Such monitoring may also be carried out via the surgeon-driven EMG monitoring system shown and described in the following commonly owned and co-pending NeuroVision PCT Applications referenced above. In any case (visual monitoring, traditional EMG and/or surgeon-driven EMG monitoring), the access system of the present invention may advantageously be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed. For example, the surgical access system may be advantageously used to traverse tissue through the retroperitoneal space and the psoas muscle during a substantially lateral, retroperitoneal approach to the lumbar spine, as shown in FIGS. **23-50**.

FIGS. **19-20** illustrate, by way of example only, a monitoring system **120** of the type disclosed in the NeuroVision PCT Applications suitable for use with the surgical access system **10** of the present invention. The monitoring system **120** includes a control unit **122**, a patient module **124**, and an EMG harness **126** and return electrode **128** coupled to the patient module **124**, and a cable **132** for establishing electrical communication between the patient module **124** and the surgical access system of the present invention (retractor assembly **10** of FIG. **1** and distraction assemblies **40, 50** of FIGS. **9-12**). More specifically, this electrical communication can be achieved by providing, by way of example only, a hand-held stimulation controller **152** capable of selectively providing a stimulation signal (due to the operation of manually operated buttons on the hand-held stimulation controller **152**)

to one or more connectors **156a**, **156b**, **156c**. The connectors **156a**, **156b**, **156c** are suitable to establish electrical communication between the hand-held stimulation controller **152** and (by way of example only) the stimulation electrodes on the K-wire **42**, the dilators **44**, **48**, **52**, **54**, the retractor blades **12**, **16**, **18** and/or the shim members **22**, **24**, **25** (collectively “surgical access instruments”).

In order to use the monitoring system **120**, then, these surgical access instruments must be connected to the connectors **156a**, **156b** and/or **156c**, at which point the user may selectively initiate a stimulation signal (preferably, a current signal) from the control unit **122** to a particular surgical access instruments. Stimulating the electrode(s) on these surgical access instruments before, during and/or after establishing operative corridor will cause nerves that come into close or relative proximity to the surgical access instruments to depolarize, producing a response in a myotome associated with the innervated nerve.

The control unit **122** includes a touch screen display **140** and a base **142**, which collectively contain the essential processing capabilities (software and/or hardware) for controlling the monitoring system **120**. The control unit **122** may include an audio unit **118** that emits sounds according to a location of a surgical element with respect to a nerve. The patient module **124** is connected to the control unit **122** via a data cable **144**, which establishes the electrical connections and communications (digital and/or analog) between the control unit **122** and patient module **124**. The main functions of the control unit **122** include receiving user commands via the touch screen display **140**, activating stimulation electrodes on the surgical access instruments, processing signal data according to defined algorithms, displaying received parameters and processed data, and monitoring system status and report fault conditions. The touch screen display **140** is preferably equipped with a graphical user interface (GUI) capable of communicating information to the user and receiving instructions from the user. The display **140** and/or base **142** may contain patient module interface circuitry (hardware and/or software) that commands the stimulation sources, receives digitized signals and other information from the patient module **124**, processes the EMG responses to extract characteristic information for each muscle group, and displays the processed data to the operator via the display **140**.

In one embodiment, the monitoring system **120** is capable of determining nerve direction relative to one or more of the K-wire **42**, the dilators **44**, **48**, **52**, **54**, the retractor blades **12**, **16**, **18** and/or the shim elements **22**, **24**, **25** before, during and/or following the creation of an operative corridor to a surgical target site. Monitoring system **120** accomplishes this by having the control unit **122** and patient module **124** cooperate to send electrical stimulation signals to one or more of the stimulation electrodes provided on these instruments. Depending upon the location of the surgical access system **10** within a patient (and more particularly, to any neural structures), the stimulation signals may cause nerves adjacent to or in the general proximity of the surgical access system **10** to depolarize. This causes muscle groups to innervate and generate EMG responses, which can be sensed via the EMG harness **126**. The nerve direction feature of the system **120** is based on assessing the evoked response of the various muscle myotomes monitored by the system **120** via the EMG harness **126**.

By monitoring the myotomes associated with the nerves (via the EMG harness **126** and recording electrode **127**) and assessing the resulting EMG responses (via the control unit **122**), the surgical access system **10** is capable of detecting the presence of (and optionally the distant and/or direction to)

such nerves. This provides the ability to actively negotiate around or past such nerves to safely and reproducibly form the operative corridor to a particular surgical target site, as well as monitor to ensure that no neural structures migrate into contact with the surgical access system **10** after the operative corridor has been established. In spinal surgery, for example, this is particularly advantageous in that the surgical access system **10** may be particularly suited for establishing an operative corridor to an intervertebral target site in a postero-lateral, trans-psoas fashion so as to avoid the bony posterior elements of the spinal column. For example, one such operative corridor to an intervertebral target site may be established through the retroperitoneal space and the psoas muscle during a substantially lateral, retroperitoneal approach to the lumbar spine, as shown in FIGS. **23-50**.

FIGS. **21-22** are exemplary screen displays (to be shown on the display **140**) illustrating one embodiment of the nerve direction feature of the monitoring system shown and described with reference to FIGS. **19-20**. These screen displays are intended to communicate a variety of information to the surgeon in an easy-to-interpret fashion. This information may include, but is not necessarily limited to, a display of the function **180** (in this case “DIRECTION”), a graphical representation of a patient **181**, the myotome levels being monitored **182**, the nerve or group associated with a displayed myotome **183**, the name of the instrument being used **184** (in this case, a dilator **46**, **48**), the size of the instrument being used **185**, the stimulation threshold current **186**, a graphical representation of the instrument being used **187** (in this case, a cross-sectional view of a dilator **44**, **48**) to provide a reference point from which to illustrate relative direction of the instrument to the nerve, the stimulation current being applied to the stimulation electrodes **188**, instructions for the user **189** (in this case, “ADVANCE” and/or “HOLD”), and (in FIG. **22**) an arrow **190** indicating the direction from the instrument to a nerve. This information may be communicated in any number of suitable fashions, including but not limited to the use of visual indicia (such as alpha-numeric characters, light-emitting elements, and/or graphics) and audio communications (such as a speaker element). Although shown with specific reference to a dilating cannula (such as at **184**), it is to be readily appreciated that the present invention is deemed to include providing similar information on the display **140** during the use of any or all of the various instruments forming the surgical access system **10** of the present invention, including the initial distraction assembly **40** (i.e. the K-wire **42** and dilators **44**, **48**) and/or the retractor blades **12**, **16**, **18** and/or the shim elements **22**, **24**, **25**.

Referring now to FIGS. **23-50**, some embodiments of the surgical access system **10** may be particularly suited for establishing an operative corridor to a surgical target site in the spine. Such an operative corridor may be established through the retroperitoneal space and the psoas muscle during a direct lateral, retroperitoneal approach to the spine. A surgeon may have direct visualization of the patient’s anatomy without the cumbersome requirements associated with using endoscopes or operating coaxial through narrow tubes. Moreover, when using the access system **10** through a lateral approach to the spine, the potential of damaging nerves while advancing instruments through the psoas muscle may be substantially reduced. It will, of course, be appreciated that the surgical access system and related methods of the present invention may find applicability in any of a variety of surgical and/or medical applications such that the following description relative to the direct lateral, retroperitoneal approach to the spine is not to be limiting of the overall scope of the present invention.

When accessing a spinal target site via the substantially lateral, retroperitoneal approach described in connection with FIGS. 23-50, the surgeon should consider several anatomical reference points, such as the iliac crest, the twelfth rib, and the lateral border of the erector spinae muscle groups. In certain 5 embodiments, blunt finger dissection is used to pass between these muscle groups and access the retroperitoneal space. Such a technique offers simple access to the retroperitoneal space while minimizing the potential of visceral lesion. Furthermore, in such embodiments, the finger may be used to 10 escort one or more dilators through the retroperitoneal space, thus reducing the potential of peritoneal disruption. In some instances, each dilator is preferably advanced through the psoas muscle between the middle and anterior third of the muscle so that the nerves of the lumbar plexus are located 15 posterior and outside the operative corridor. A monitoring system 120 of the type disclosed in the NeuroVision PCT Applications may be used to avoid damage to any peripheral nerves embedded throughout the psoas muscle as the dilator is advanced through the muscle to the surgical target site in the spine.

Referring now to FIGS. 23-24, a patient 200 is positioned on a surgical table 250 in preparation of spinal surgery. In some embodiments, a cushion 252 is positioned between the patient's lateral side and the surgical table 250 to arrange the patient 200 in such a way as to increase the distance between the patient's iliac crest 202 and rib cage 204. Alternatively, a flexion of the surgical table 250 may be used to accomplish the desired arrangement. Such an arrangement helps to open the intervertebral disc space 206 at or near the surgical target site.

Referring to FIG. 25, an articulating arm assembly 60 is coupled to the surgical table 250 to maintain the access system 10 in a substantially fixed position relative to the surgical target site when the operative corridor has been established. In this embodiment, the articulating arm assembly 60 is mounted to a bedrail 254 of the surgical table 250. In some instances, a fluoroscopy system 260 is disposed proximal to the surgical table 250 to provide the surgeon with visualization of the surgical target area. This fluoroscopy system 260 40 includes a display monitor 262 that is positioned such that the surgeon may view the monitor 262 during the operation. In addition, a monitoring system 120 of the type disclosed in the NeuroVision PCT Applications may be positioned near the surgical table 250 so that the surgeon may view a display 140 45 of the monitoring system 120 during the operation.

Referring now to FIGS. 26-28, one or more instruments, such as K-wires 42, are positioned laterally over an area of the patient 200 and then viewed using the lateral fluoroscopy. The instruments are used to identify a lateral incision location 208 50 that is substantially lateral to the surgical target site (e.g., the intervertebral disc space 206). As shown in FIG. 28, a first mark is made on the patient 200 at the lateral incision location 208. In addition, a second mark is made on the patient at a posteriolateral incision location 209 near the lateral incision location 208. In this embodiment, the posteriolateral incision location 209 is approximately at the lateral border of the erector spine muscle. Preferably, the posteriolateral incision location 209 is within a finger's length of the lateral incision location 208.

Referring to FIG. 29, an incision is made at the posteriolateral incision location 209, and the subcutaneous layers 210 are dissected until reaching the muscular masses 212. A dissection instrument, such as blunt dissection scissors 270, is used to spread the muscle fibers 212 until the retroperitoneal space 215 is reached. Preferably, the surgeon uses great caution to avoid perforation of the peritoneum 214.

Referring to FIGS. 30-31, after the retroperitoneal space 215 is reached, a guide member 275 is inserted through the posteriolateral incision 209 into the retroperitoneal space 215. In a presently preferred embodiment, the guide member 5 is a finger 275 of the surgeon, which is preferably covered with a surgical glove for hygienic purposes. In other embodiments, the guide member 275 may be an instrument or tool configured to extend and maneuver in the retroperitoneal space as described herein. As shown in FIGS. 30-31, the finger 275 may sweep a portion of the retroperitoneal space 215 and then palpate down to the psoas muscle 220. This motion of the finger 275 in the retroperitoneal space 215 may loosen some fatty tissue before a dilator is advanced there-through.

Referring to FIGS. 32-33, after the psoas muscle 220 is identified, the finger 275 is swept away from the psoas muscle 220 toward the lateral incision location 208. A scalpel 272 or other like instrument is used to make an incision at this location 208. The incision should be of a sufficient size to 20 receive a distal end 41 of an initial dilator 40.

Referring to FIGS. 34-35, the finger 275 is used to direct the distal end 41 of the initial dilator 40 through the retroperitoneal space 215 toward the psoas muscle 220. In the presently preferred embodiment, the initial dilator 40 includes at least a K-wire 42 and may also include a split-dilator 48 25 slideably passed over the K-wire 42 (see, for example, FIG. 10). As shown in FIG. 34, the distal end 41 is introduced through the lateral incision location 208 and directed to the finger 275 in the retroperitoneal space 215. As shown in FIG. 35, the finger 275 engages the initial dilator 40 proximal to the distal end 41 and guides the distal end 41 to the psoas muscle 220. By escorting the dilator 40 through the retroperitoneal space 215 using the finger 275, the potential for breaching or disrupting the peritoneum is reduced. Upon reaching the psoas muscle 220, the location of the distal end 41 relative to the target site may be verified using an imaging system, such as an image intensifier.

Referring to FIGS. 36-37, the distal end 41 of the initial dilator 40 is advanced in a substantially lateral direction through the psoas muscle 220 toward the intervertebral disc space 206 at or near the surgical target site. In the presently preferred embodiment, the fibers of the psoas muscle 220 are split using blunt dissection and NeuroVision neurophysiologic monitoring of the type disclosed in the NeuroVision PCT Applications. A stimulation connector 156 of the NeuroVision monitoring system 120 (see FIG. 19) is coupled to the initial dilator 40 to provide a stimulation signal 157 as the dilator 40 is advanced through the psoas muscle 220. It should be understood that the stimulation signal 157 is depicted in 50 FIG. 36 for illustrative purposes and is generally not visible.

Descending nerves of the lumbar plexus normally lie in the posterior one-third of the psoas muscle 220. The NeuroVision monitoring system 120 of the type disclosed in the NeuroVision PCT Applications assists with the safe passage by these nerves and/or confirmation of the nerves' posterior location. The NeuroVision monitoring system 120 will continuously search for the stimulus threshold that elicits an EMG response on the myotomes monitored and then reports such thresholds on a display 140 as shown in FIG. 37. As the dilator is 60 advanced through the psoas muscle 220, the stimulus necessary to elicit an EMG response will vary with distance from the nerve. In the presently preferred embodiment, experience has shown that threshold values greater than 10 mA indicate a distance that allows for safe passage through the psoas muscle 220 and continued nerve safety.

Referring to FIGS. 38-40, a K-wire 42 of the initial dilator 40 is introduced into the targeted disc space 206 after the

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dilator **40** is passed through the psoas muscle **220**. Preferably, the position of the distal end **41** of the dilator **40** is confirmed using fluoroscopic imaging before the K-wire **42** is introduced into the disc space **206**. After a distal portion of the K-wire **42** is inserted into the targeted disc space **206**, depth markings **45** (FIG. **39**) on the dilator **40** may be read at the skin level to determine the appropriate length of retractor blades **12**, **16**, **18** that will be used with the handle assembly **20** of the access system **10**. As shown in FIG. **40**, the appropriate length blades **12**, **16**, and **18** may be secured to the handle portion **20** by tightening fasteners with a driver instrument **274**.

Referring to FIG. **41**, the sequential dilation system **50** (previously described in connection with FIG. **12**), including one or more supplemental dilators **52**, **54**, may be guided over the initial dilator **40** for the purpose of further dilating the tissue down to the surgical target site. In the presently preferred embodiment, the NeuroVision monitoring system **120** of the type disclosed in the NeuroVision PCT Applications is used with the supplemental dilators **52**, **54** to provide safe passage through the psoas muscle **220**. The initial dilator **40** and the supplemental dilators **52**, **54** are advanced through the lateral incision location **208** to the targeted disc space **206** in a substantially lateral direction to create a distraction corridor.

Still referring to FIG. **41**, the retractor blades **12**, **16**, **18** of the access system **10** are introduced over the supplemental dilator **54** (or the initial dilator **40** if the sequential dilation system **50** is not employed) toward the disc space **206**; Again, the NeuroVision monitoring system **120** of the type disclosed in the NeuroVision PCT Applications may be used with the blades **12**, **16**, **18** to provide safe passage through the psoas muscle **220**. In some embodiments, the posterior shim element **22** and/or the retractor extenders **24**, **25** are engaged with the retractor blades **12**, **16**, **18** (as previously described in connection with FIGS. **1-7**). After the retractor blades **12**, **16**, **18** are introduced along the distraction corridor, fluoroscopic imaging may be used to confirm the position of the blades **12**, **16**, **18** proximal to the disc space **206**.

Referring to FIG. **42**, the articulating arm assembly **60** is coupled to the handle member **20** of the access system **10**. As previously described in connection with FIG. **25**, the articulating arm assembly **60** is also coupled to the surgical table **250** so as to maintain the access system **10** in a substantially fixed position. Handles **62** and **64** may be turned to substantially fix the position of articulating arm assembly **60**.

Referring now to FIGS. **43-44**, handle extenders **31** and **33** may be squeeze to spread the blades **12**, **16**, **18** and knob members **36** may be turned to selectively adjust the posterior retractor blade **12** (previously described in connection with FIGS. **13-18**). Such movement by the blades **12**, **16**, **18** retracts the distraction corridor so as to form an operative corridor **15**.

FIG. **45** shows a lateral view of the operative corridor **15** down to the targeted disc space **206** in the patient's spine. Light emitting devices **39** may be coupled to one or more of the retractor blades **12**, **16**, **18** to direct light down the operative corridor **15**. In this embodiment, the light emitting devices **39** are coupled to a xenon arthroscopy light source. The surgeon may use direct visualization and/or a NeuroVision probe of the type disclosed in the NeuroVision PCT Applications to confirm that the operative corridor **15** is neurologically clear.

Referring to FIGS. **46-50**, various instruments may be inserted through the operative corridor **15** to prepare the targeted disc space **206**. In the presently preferred embodiment, the operative corridor **15** has a 15-20 mm annulotomy to provide ample space for the various instruments. In other

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embodiments, the operative corridor **15** may have other configurations, depending on the surgical task to be performed.

In this embodiment depicted in FIGS. **46-50**, the disc space **206** is undergoing a discectomy and insertion of a spinal implant. As shown in FIG. **46**, at least one preparation tool **276** such as a disc cutter, pituitary, scraper, curette, or the like is inserted through the operative corridor **15** to prepare the disc space **206**. Referring more closely to FIG. **47**, one or more sizers **277** are inserted to the disc space **206** to provide appropriate disc height restoration. As shown in FIG. **48**, a broach **278** may be used in the disc space **206** to remove osteophytes and to facilitate implant insertion.

Referring now to FIGS. **49-50**, an appropriately sized implant **282** is advanced into the disc space **206** with an inserter tool **280**. The implant **282** is releasably secured to the inserter tool **280** such that the surgeon may release the implant when it is properly positioned in the disc space **206**. The implant may comprise a material that facilitates bone fusion (such as allograft or autograft), and autograft or graft extenders may be used in the disc space **206** after the implant is inserted.

After the procedure on the targeted disc space **206** is complete, the access system **10** is carefully removed from the operative corridor **15**. Direct visualization may be used to confirm the absence of significant bleeding in the disc space **206** or the psoas muscle **220**. The skin around the operative corridor may be closed using a suturing method, such as a subcuticular suture.

Accordingly, certain methods of using the access system **10** can safely and effectively establish a minimally invasive operative corridor through the retroperitoneal space **215** and the psoas muscle **220** via a direct lateral, retroperitoneal approach to the spine. Such a method allows the surgeon to directly visualize the patient's anatomy without the cumbersome requirements associated with using endoscopes or operating coaxial through narrow, artificial tube. Moreover, when employing such a method to laterally approach the spine, the potential of damaging nerves while advancing dilators and other instruments through the psoas muscle **220** may be substantially reduced.

As evident from the above discussion and drawings, the present invention accomplishes the goal of gaining access a surgical target site in a fashion less invasive than traditional "open" surgeries and, moreover, does so in a manner that provides the ability to access such a surgical target site regardless of the neural structures required to be passed through (or near) in order to establish an operative corridor to the surgical target site. The present invention furthermore provides the ability to perform neural monitoring in the tissue or regions adjacent the surgical target site during any procedures performed after the operative corridor has been established. The surgical access system of the present invention can be used in any of a wide variety of surgical or medical applications, above and beyond the spinal applications discussed herein. Such spinal applications may include any procedure wherein instruments, devices, implants and/or compounds are to be introduced into or adjacent the surgical target site, including but not limited to discectomy, fusion (including PLIF, ALIF, TLIF and any fusion effectuated via a lateral or far-lateral approach and involving, by way of example, the introduction of bone products (such as allograft or autograft) and/or devices having ceramic, metal and/or plastic construction (such as mesh) and/or compounds such as bone morphogenic protein), total disc replacement, etc. . . .

Moreover, the surgical access system of the present invention opens the possibility of accessing an increased number of surgical target sites in a "less invasive" fashion by eliminating

or greatly reducing the threat of contacting nerves or neural structures while establishing an operative corridor through or near tissues containing such nerves or neural structures. In so doing, the surgical access system of the present invention represents a significant advancement capable of improving patient care (via reduced pain due to “less-invasive” access and reduced or eliminated risk of neural contact before, during, and after the establishment of the operative corridor) and lowering health care costs (via reduced hospitalization based on “less-invasive” access and increased number of suitable surgical target sites based on neural monitoring). Collectively, these translate into major improvements to the overall standard of care available to the patient population, both domestically and overseas.

What is claimed is:

**1.** A method included in providing surgical access to a spinal target site in a human patient through a substantially lateral, retroperitoneal approach, the method comprising:

inserting at least a portion of a finger of a surgeon through a first, posteriolateral incision and into a retroperitoneal space;

sweeping at least a portion of the finger in the retroperitoneal space;

inserting a distal tip of a dilation member through a second, substantially lateral incision and into the retroperitoneal space;

using at least a portion of the finger to guide the distal tip of the dilation member within the retroperitoneal space toward a psoas muscle; and

advancing the distal tip of the dilation member in a substantially lateral direction through the psoas muscle toward a spinal target site while using a stimulation electrode on the dilation member to monitor for the presence of nerves in the vicinity of the dilation member.

**2.** The method of claim **1**, wherein the dilation member is an initial dilator.

**3.** The method of claim **1**, further comprising operating a control unit to electrically stimulate said stimulation electrode, sensing a response of a nerve depolarized by said stimulation, and determining a direction from the dilation member to the nerve based upon the sensed response.

**4.** The method of claim **1**, further comprising creating a distraction corridor by advancing one or more secondary dilators over the dilation member to sequentially widen said distraction corridor.

**5.** The method of claim **4**, wherein creating said distraction corridor comprises monitoring for the presence of nerves using at least one stimulation electrode on at least one of the secondary dilators.

**6.** The method of claim **5**, wherein said monitoring for the presence of nerves that is part of said creating of said distraction corridor includes operating a control unit to electrically stimulate said at least one stimulation electrode on the at least one of the secondary dilators, sensing a response of a nerve depolarized by said stimulation, and determining a direction from said at least one of the secondary dilators to the nerve based upon the sensed response.

**7.** The method of claim **1**, further comprising retracting a distraction corridor to produce a substantially lateral operative corridor to said spinal target site.

**8.** The method of claim **7**, wherein retracting said distraction corridor comprises:

simultaneously introducing a plurality of retractor blades into said distraction corridor; and

opening said plurality of retractor blades to create an operative corridor to said spinal target site.

**9.** A method of accessing a spinal target site in a human patient, comprising:

creating a distraction corridor to a spinal target site through a substantially lateral, retroperitoneal approach, comprising:

inserting at least a portion of a finger of an operating surgeon through a first, posteriolateral incision and into a retroperitoneal space,

sweeping at least a portion of the finger in the retroperitoneal space;

inserting a distal end of a dilation member through a second, substantially lateral incision and into the retroperitoneal space, using at least a portion of the finger to guide the distal end of the dilation member

within the retroperitoneal space, and

advancing the dilation member in a substantially lateral direction toward the spinal target site; and

retracting said distraction corridor to produce an operative corridor to said spinal target site.

**10.** The method of claim **9**, wherein the dilation member is an initial dilator.

**11.** The method of claim **10**, wherein the initial dilator includes at least a K-wire.

**12.** The method of claim **9**, wherein creating said distraction corridor includes operating one or more secondary dilators to sequentially widen said distraction corridor.

**13.** The method of claim **9**, wherein at least one of creating said distraction corridor and retracting said distraction corridor comprises monitoring for the presence of nerves using at least one stimulation electrode.

**14.** The method of claim **13**, wherein monitoring for the presence of nerves includes operating a control unit to electrically stimulate said at least one stimulation electrode, sensing a response of a nerve depolarized by said stimulation, and determining a direction from at least one of the dilation member and a retractor to the nerve based upon the sensed response.

**15.** The method of claim **9**, wherein retracting said distraction corridor comprises:

simultaneously introducing a plurality of retractor blades into said distraction corridor; and

opening said plurality of retractor blades to create an operative corridor to said surgical target site.

**16.** The method of claim **15**, wherein the plurality of retractor blades are simultaneously introduced to the surgical target site while in a generally closed position.

**17.** The method of claim **15**, wherein the plurality of retractor blades are opened by selectively moving said retractor blades to create a customized operative corridor to said surgical target site.

**18.** The method of claim **1**, wherein the patient is positioned in a lateral decubitus position during the method.

**19.** The method of claim **1**, further comprising using at least a portion of the finger to palpate a lateral aspect of the psoas muscle prior to inserting the distal tip of the dilation member.

**20.** The method of claim **1**, wherein the step of sweeping at least a portion of the finger comprises sweeping the peritoneal cavity anteriorly.

**21.** The method claim **1**, wherein the step of sweeping at least a portion of the finger comprises loosening fatty tissue in the retroperitoneal space.

**22.** The method claim **1**, wherein the spinal target site comprises an intervertebral disc space in a lumbar spine.

**23.** The method of claim **1**, further comprising inserting a plurality of sequential dilators over the dilation member in the substantially lateral direction through the psoas muscle.



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**24.** The method of claim **9**, wherein the patient is positioned in a lateral decubitus position during the method.

**25.** The method of claim **9**, further comprising using at least a portion of the finger to palpate a lateral aspect of a psoas muscle prior to inserting the distal end of the dilation member. 5

**26.** The method of claim **9**, wherein the step of sweeping at least a portion of the finger comprises sweeping the peritoneal cavity anteriorly.

**27.** The method claim **9**, wherein the step of sweeping at least a portion of the finger comprises loosening fatty tissue in the retroperitoneal space. 10

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**28.** The method claim **9**, wherein the spinal target site comprises an intervertebral disc space in a lumbar spine.

**29.** The method of claim **9**, wherein the step of creating the distraction corridor further comprises inserting a plurality of sequential dilators over the dilation member in the substantially lateral direction through the psoas muscle.

**30.** The method of claim **2**, wherein the initial dilator includes at least a K-wire.

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(12) **INTER PARTES REEXAMINATION CERTIFICATE** (1504th)

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**Pimenta et al.**

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(54) **SURGICAL ACCESS SYSTEM AND RELATED METHODS**

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(58) **Field of Classification Search**

None  
See application file for complete search history.

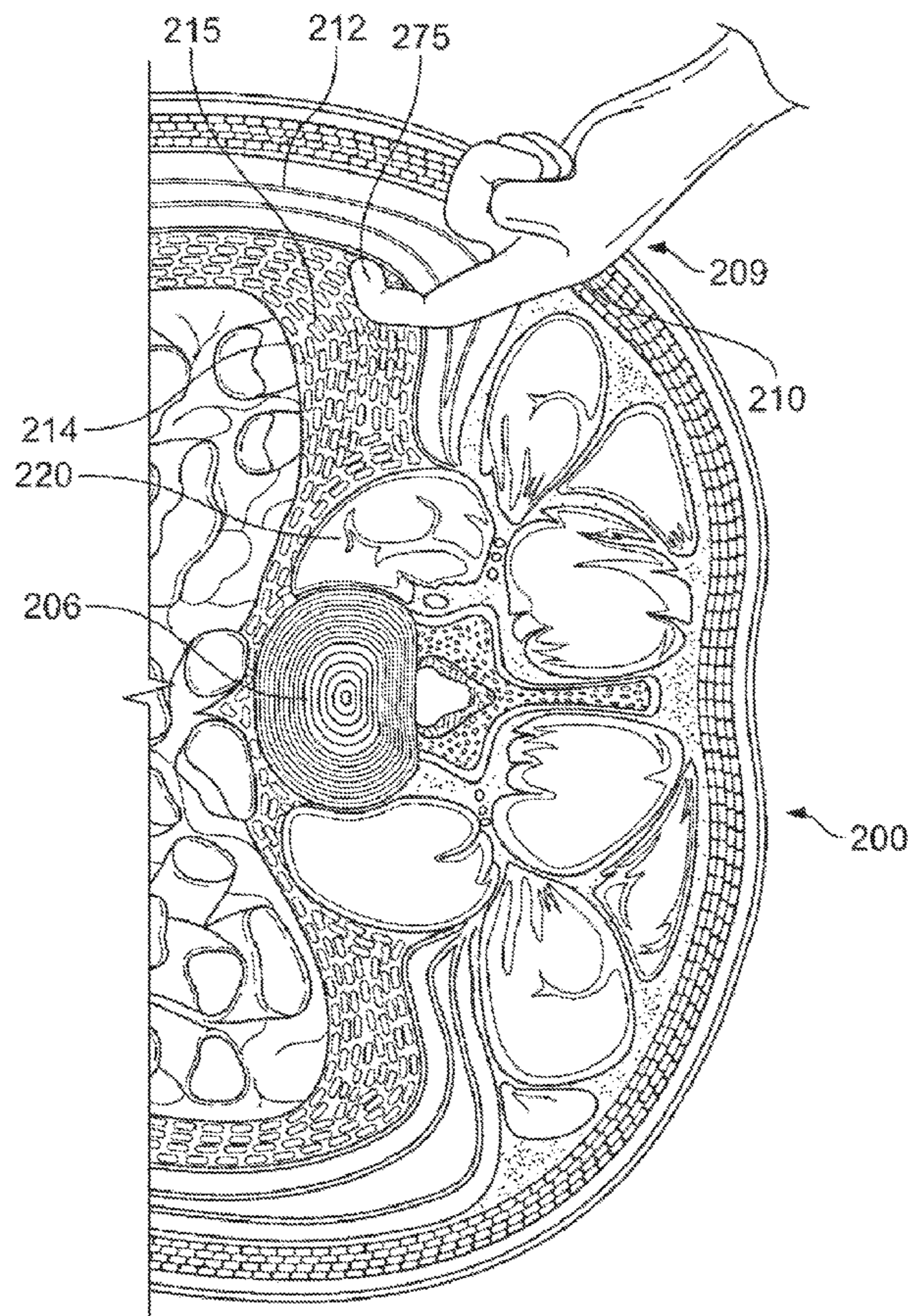
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To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 95/001,890, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

*Primary Examiner* — Catherine S Williams

(57) **ABSTRACT**

A surgical access system including a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor to a surgical target side. Some embodiments of the surgical access system may be particularly suited for establishing an operative corridor to a surgical target site in the spine. Such an operative corridor may be established through the retroperitoneal space and the psoas muscle during a direct lateral, retroperitoneal approach to the spine.



**INTER PARTES  
REEXAMINATION CERTIFICATE**

THE PATENT IS HEREBY AMENDED AS  
INDICATED BELOW.

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AS A RESULT OF REEXAMINATION, IT HAS BEEN  
DETERMINED THAT:

Claims **1-10**, **12-15** and **17-29** are cancelled.

10

Claims **11**, **16** and **30** were not reexamined.

\* \* \* \* \*